PB80-181944

The Health Consequences of Sulfur Oxides
A Report from CHESS (Community Health and
Environmental Surveillance System)
1970-1971, May, 1974. Appendum

(U.S.) Environmental Protection Agency
Washington, DC

Apr 80

U.S. Department of Commerce
National Technical Information Service
NTIS

United States
Environmental Protection
Agency

EPA-600/1-80-021
April 1980

Research and Development

PB80-181944

EPA

Addendum to

"The Health Consequences of Sulfur Oxides: A Report from CHESS, 1970-1971," May 1974

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TECHNICAL REPORT DATA

(Please read Instructions on the reverse before completing)

1. REPORT NO.
EPA-600/1-80-021

2.

3. RECIPIENT'S ACCESSION NO.
PB 80 181944

4. TITLE AND SUBTITLE
Addendum to "The Health Consequences of Sulfur Oxides:
A Report from CHESS, 1970-17971," May 1974

5. REPORT DATE
April 1980 issuing date

6. PERFORMING ORGANIZATION CODE

7. AUTHOR(S)

8. PERFORMING ORGANIZATION REPORT NO.

9. PERFORMING ORGANIZATION NAME AND ADDRESS

10. PROGRAM ELEMENT NO.

11. CONTRACT/GRANT NO.

12. SPONSORING AGENCY NAME AND ADDRESS
Office of Research and Development
U.S. Environmental Protection Agency
Washington, DC 20460

13. TYPE OF REPORT AND PERIOD COVERED

14. SPONSORING AGENCY CODE
EPA/600/00

15. SUPPLEMENTARY NOTES
Original report, EPA-650/1-74-004; available from NTIS PB 234-920

16. ABSTRACT

A controversy about the scientific credibility of results from the Community Health and Environmental Surveillance System (CHESS) study prompted a series of Congressional hearings in 1976 ("The Brown Report") with subsequent legislation (Public Law 95-155) to enact the Environmental Research, Development and Demonstration Authorization Act of 1978. This addendum has been compiled to satisfy Recommendation 3(c) of The Brown Committee Report, entitled "The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report." It contains the following materials which concern the 1974 CHESS Monograph and various CHESS studies, in addition to EPA's research and development program in general: as follows The Brown Committee Report; P.L. 95-155; Appendices from EPA's Research Outlook for 1978 and 1979; and the Science Advisory Board's Health Effects Research Review Group Report to Congress in February 1979.

17. KEY WORDS AND DOCUMENT ANALYSIS

a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group

18. DISTRIBUTION STATEMENT
RELEASE TO PUBLIC

19. SECURITY CLASS *(This Report)*
UNCLASSIFIED

20. SECURITY CLASS *(This page)*
UNCLASSIFIED

21. NO. OF PAGES

22. PRICE

EPA Form 2220-1 (Rev. 4-77) PREVIOUS EDITION IS OBSOLETE

Addendum
to

"The Health Consequences
of Sulfur Oxides: A Report
from CHESS, 1970-1971,"
May 1974

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Introduction

This document is an addendum to the 1974 monograph published by the U.S. Environmental Protection Agency, titled "Health Consequences of Sulfur Oxides: A Report from CHESS, 1970-1971" (EPA-650/1-74-004). A key portion of the addendum is a copy of a Congressional report which contained recommendations to EPA regarding the 1974 monograph and the conduct of health research generally. Also included are reports to Congress by both EPA and the Science Advisory Board on the Agency's implementation of these recommendations. The Congressional report and subsequent legislation which bears on the Agency's compliance with the report's recommendations are described below.

In 1976, the Subcommittees on Oversight and on Environment and the Atmosphere of the House Committee on Science and Technology released an evaluative report on EPA air pollution research programs. The report, titled "The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report," is commonly referred to as "the Brown Committee Report." The report sets forth in detail findings and recommendations regarding epidemiologic investigations carried out by EPA into the human health effects from air pollution. In particular, the report critically addressed the 1974 monograph, which analyzed CHESS studies related to the health consequences of sulfur oxides. Also addressed was the effectiveness of EPA's total research and development program.

In 1977, Congress enacted the Environmental Research, Development, and Demonstration Authorization Act of 1978 ("ERDDAA"), P.L. 95-155, November 8, 1977. Section 8(a) of ERDDAA provided a statutory basis for EPA's Science Advisory Board ("SAB").* Section 8(c) directed that when the Administrator for EPA submits his annual report to Congress on the Agency's five-year plan for research, development, and demonstration, it be accompanied by the SAB's comments on the plan. Section 8(d) further directed that the SAB independently report to Congress on EPA's health effects research generally and on the findings and recommendations of the Brown Committee Report in particular.

Section 10 of ERDDAA specifically required the Administrator of EPA to implement the recommendations of the Brown Committee Report, unless he makes certain determinations. Section 10 also requires the Administrator to report to Congress on the status of implementation of the Brown Committee recommendations in each annual report he makes on EPA's five-year plan for research and development.

Recommendation 3(c) of the Brown Committee Report was that EPA should publish an addendum to the 1974 monograph, containing at a minimum chapters IV, V, and VI and Appendix A of the Brown Report. This publication constitutes such an addendum to the monograph. As set forth below, the addendum contains various materials which concern not only the 1974 monograph and the various CHESS studies, but also EPA's research and development program generally.

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*The SAB was originally established by EPA in 1974 in order to provide advice to the Administrator on scientific and technical aspects of environmental regulation. By providing a statutory foundation, Congress intended to enhance the status, scope and responsibilities of the SAB.

Included as Part 1 of the addendum is the entire Brown Committee Report.

Part 2 contains appendices from EPA's Research Outlook reports for 1978 and 1979, each of which include discussions of compliance with the Brown Committee recommendations. The Research Outlook reports are EPA's annual reports to Congress on the Agency's five-year plans for research and development. The availability of these appendices as further information on the Sulfur Oxides monograph was previously noticed in the Federal Register of March 7, 1979 (44FR 12490).

Finally, Part 3 contains a report made to Congress in February 1979, by the SAB's Health Effects Research Review Group ("HERRG"). The HERRG report, as required by Section 8(d) of ERDDAA, summarizes the nature of health effects research at EPA and reports on steps taken by EPA to implement the recommendations of the Brown Committee.

Part 1

Congressional Report to EPA (1976) and subsequent legislation which bears on the Agency's compliance with the report's recommendations.

[COMMITTEE PRINT]

THE ENVIRONMENTAL PROTECTION AGENCY'S RESEARCH PROGRAM

WITH PRIMARY EMPHASIS ON THE

COMMUNITY HEALTH AND ENVIRONMENTAL SURVEILLANCE SYSTEM (CHESS): AN INVESTIGATIVE REPORT

REPORT

PREPARED FOR THE

SUBCOMMITTEE ON SPECIAL STUDIES,
INVESTIGATIONS AND OVERSIGHT

AND THE

SUBCOMMITTEE ON THE ENVIRONMENT
AND THE ATMOSPHERE

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES
NINETY-FOURTH CONGRESS
SECOND SESSION
Serial SS

NOVEMBER 1976

Printed for the use of the Committee on Science and Technology

U.S. GOVERNMENT PRINTING OFFICE
77-590 WASHINGTON : 1976

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402 - Price $1.35

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LETTER OF TRANSMITTAL

House of Representatives,
Committee on Science and Technology,
Washington, D.C., November 19, 1976.

Hon. Olin E. Teague,
Chairman, Committee on Science and Technology, U.S. House of Representatives, Washington, D.C.

Dear Mr. Chairman: I am transmitting herewith a report entitled "The Environmental Protection Agency's Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report." This report provides the conclusions and recommendations resulting from an intensive evaluation of the scientific and technical adequacy of this important air pollution-health effects surveillance system and related research programs. The report indicates that there are a number of serious issues in EPA's research programs which require resolution in order to achieve more effective results.

The report was prepared by Committee staff members, Dr. R. B. Dillaway, Science Consultant and Director, EPA CHESS Investigation, and Oversight Subcommittee on Special Studies, Investigations Task Team Leader, and Dr. Radford Byerly, Jr., Science Consultant, Subcommittee on the Environment and the Atmosphere, who was detailed to assist in the investigation. Committee staff members were assisted in the preparation of the report and in the conduct of the on-site investigation by a special team of consultants. The Committee is grateful for the cooperation of the agencies which permitted their participation and expresses appreciation to the consultants for their assistance. The special consultants were: Mitchell H. Gail, M.D., Medical Statistical Researcher, Biometry Branch, National Cancer Institute; Paul A. Humphrey, Senior Scientist (Retired), Division of Meteorology, EPA/NOAA, National Oceanic and Atmospheric Administration; Dr. James M. McCullough, Senior Specialist in Science and Technology (Life Sciences), Science Policy Research Division, Congressional Research Service, Library of Congress; Cdr. John W. Poundstone, M.D., Chief, Occupational and Preventive Medicine, Navy Regional Medical Center, Great Lakes; Dr. Harry L. Rook, Chief, Activation Analysis Section, Analytical Chemistry Division, National Bureau of Standards; and Charles C. VanValin, Research Chemist, Atmospheric Physics and Chemistry Laboratory, Environmental Research Laboratories, National Oceanic and Atmospheric Administration. In addition, the Committee staff solicited the opinions and advice of a number of other scientists, statisticians, and physicians in other agencies and institutes.

In accordance with your direction, the staff in this investigation reported to me. I have nothing but praise for the professional manner with which they carried out the study. I have carefully reviewed this report and am prepared to take full responsibility for its contents. I further recommend its adoption as a Science and Technology Committee report.

In closing, however, I would like to make an additional observation that goes beyond this particular study. The need to regulate pollutants in this industralized age is likely to grow, not diminish. Regulating knowledgeably is therefore essential. This report provides several examples of the many instances in which the status of environmental research and technology is not what it should be to assure adequate and well founded protection of human health. While this investigative report has much significance with regard to research management and execution, it does not provide all the answers to the policymaker who is obliged to act in the face of less than certain proof. The policy oriented questions of "acceptable risk" and "burden of proof" can be assisted, but never fully answered by better research. I would hope that those who read this report will not use it to undermine the minimal research work that is now underway, but instead will use it as a reason to improve and enhance the on-going programs.

Sincerely,

George E. Brown, Jr., *Chairman,*
Subcommittee on the Environment and the Atmosphere.

I. EXECUTIVE SUMMARY

The Staffs of the Subcommittee on Special Studies, Investigations and Oversight and the Subcommittee on the Environment and the Atmosphere have completed an evaluation of the Environmental Protection Agency's research program related to the health effects of air pollution, with primary emphasis on the Community Health and Environmental Surveillance System (CHESS). This investigation was noted earlier in the report on joint hearings held by the House Interstate and Foreign Commerce Committee and the House Science and Technology Committee, April 9, 1976.[1] While the joint hearings, held to determine whether there had been any deliberate distortion of data during the writing of the 1974 CHESS Monograph,[2] produced general agreement that no basis existed to question the integrity or scientific honesty of the project leader for the first CHESS Monograph, the hearings did not resolvemany questions and supported the need for a comprehensive evaluation of the scientific and technical aspects of the CHESS program and related Environmental Protection Agency (EPA) research efforts.

The investigation reported herein was conducted by a team composed of members of the staff of the House Science and Technology Committee with the support of consulting specialists in aerometry and analytical chemistry, meteorology, epidemiology, medicine, and general environmental health. Conferences were held on site, in the field, with individuals in EPA and in State and local government, academic, and private institutions who had detailed knowledge of the conduct of the CHESS programs. A number of findings and recommendations are provided in the report including those highlighted in the balance of this summary.

To some the findings may appear overly critical since CHESS pioneered in a difficult research area. However, in part the report is meant retroactively to complement the CHESS Monograph which fails to fully appraise the reader of the errors, deficiencies, and other shortcomings in the information presented in the Monograph. The intent of the report is to aid in assessing the validity of the conclusions presented in the Monograph and to assist researchers performing similar studies in avoiding similar problems. The endeavor was greatly assisted by hindsight and by the splendid cooperation and self-examination by investigators both inside and outside of the Environmental Protection Agency. The report also notes where problems similar to those found in CHESS research still exist in the EPA program.

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[1] U.S. Congress. House Interstate and Foreign Commerce and House Science and Technology Committee. 94th Congress, 2nd Session. Report on Joint Hearings on the Conduct of the Environmental Protection Agency's "Community Health and Environmental Surveillance System" (CHESS) Studies. Washington, U.S. GPO April 9, 1976.

[2] U.S. Environmental Protection Agency. Health Consequences of Sulfur Oxides: A Report from CHESS, 1970-1971. May 1974. EPA-650/1-74-004.

The report identifies the need to reexamine the wisdom of legislative and executive pressures for rapid development of information for pollution control standards, and the adverse impact of these requirements on the performance of research. Also identified were the problems which are occurring because of the Office of Management and Budget (OMB) assuming operational control over details in the EPA research programs.

The CHESS program has historical value as a first attempt at a broad based definitive study relating air quality to health effects in a precise, quantitative manner. The program is a contribution to the general field of air pollution epidemiological studies. However, many problems critical to obtaining useful quantitive results were not solved in the conduct of this research. This failure to solve procedural problems became obvious when the studies were examined. There were too many inconsistencies in the data and too many technical problems that resulted in large data uncertainties or errors associated with the aerometrics for the results of this program to provide quantitative support for policy decisions. The $25\ \mu g/m^3$ lower sensitivity limit of the method used for most SO_2 measurements coupled with the overall large error band on all measurements (possibly exceeding 100%) and the apparent bias of SO_2 concentration data on the low side, make most of the numbers presented in the CHESS Monograph unuseable. In particular, the data are too imprecise and inaccurate in the range of the SO_2 standard ($80\ \mu g/m^3$) to allow the determination of any health effects threshold. For these reasons the "hockey-stick" curves have no apparent basis in the data.

Further, there are inadequate data in the Monograph for interested researchers to evaluate fully the many caveats required for interpretation of the conclusions. For this reason, it is recommended that the EPA issue a formal notice of clarification and limitations to usage of the CHESS Monograph. In addition, EPA should prepare an addendum to the Monograph pointing out, in specific detail, the limitations of the Monograph. This addendum should: (1) Contain at least the material presented in Chapters I, IV, V, and VI, and Appendix A of this report; (2) Be made a part of any future printings of the Monograph; and (3) Be made available to the public and described in the formal notice mentioned above. EPA should not use data in the 1974 CHESS Monograph as supportive justification for policy decisions without explicit qualification and should avoid unqualified reference to the document in public information statements or documents. Further, the EPA should be encouraged to point out in any references to the 1974 CHESS Monograph that serious investigators should obtain all available data on the studies before continuing investigations of the same or similar phenomena. It is critical that EPA establish with high priority an adequately supported program to correct rapidly the kinds of deficiencies in research execution which are reported in this document. Only when the proper capabilities are established should major air quality health effects programs be renewed.

To recapitulate—the overall CHESS experience, as exemplified in the Monograph, teaches two outstanding lessons:

First, CHESS corroborates the notion that elevated air pollution levels cause adverse health effects.

Second, CHESS points out the many difficult problems involved in carrying out air pollution/health effects research.

Of course, the first lesson had been learned long ago, but failures in CHESS planning and execution precluded the development of new quantitative information on the relationship of air quality to health. Thus, CHESS cannot be called a major advance, only a confirmation of previous advances. With respect to the second lesson, the value of the CHESS experience lies mainly in the use to be made of it in correcting and improving operational procedures and research tools (i.e., instrumentation, questionnaires) and in planning future health effects studies. Finally, it seems that both these lessons could have been learned at much less cost in funds, elapsed time, EPA credibility, and staff morale.

EPA has only recently been reorganized to modify the National Environmental Research Center concept. This reorganization was examined in more detail in a previous report.[3]

The results of this present investigation suggest that the changes made last year are less effective than anticipated. The issue of research management should be continuously monitored to build the Environmental Research Center, Research Triangle Park capability and reputation. At the end of the 1977 fiscal year the situation should be examined to determine further need for reorganization. Perhaps consideration should be given now to some structure which provides for a single point of review at both the Research Triangle Park and Headquarters in order to alleviate the obvious lack of coordination of multidisciplinary projects, without attempting a major reorganization.

There is considerable evidence from this investigation that some critical disciplines, such as quality control, monitoring and sampling, and statistical analysis continue to be inadequately addressed in preproject planning of health effects studies.

In the area of research management, the investigative team's recommendations are critical of the control of research programs within EPA. There is also concern with the fact that research is being conducted by other EPA offices involving little coordination with the Office of Research and Development. This functional overlap is beginning to produce problems within the laboratories and needs to be effectively resolved before these programs continue much further. Related to this overlap and the need for the solution of the problem of poor communication between the offices and laboratories, are the needs to provide for a more effective input from the Science Advisory Board, to establish a permanent peer review system to insure coordination among laboratories, and to expedite the timely publication of research results.

Although the Administrator of EPA had indicated during the joint hearings that there was a five year plan for research on sulfates, the investigative team found that only draft plans of this program were available and that the development of this plan was being poorly coordinated. Accordingly, no specific recommendations with regard to this plan can be provided. However, the need for better information on the species of chemicals, including sulfates, which are of primary importance in health effects is emphasized and this recommendation has direct relevance to the proposed sulfate program.

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[3] U.S. Congress, House Committee on Science and Technology. Organization and Management of EPA's Office of Research and Development, 94th Congress, 2nd Session. June 1976. U.S. GPO. Washington, D.C. Serial LL 40 pp.

A number of other recommendations are made with regard to the need for improvements in the air monitoring and quality control programs, the need for additional strength in meteorology, and a number of specific suggestions about improvements in the type of epidemiological studies reported in the CHESS document.

It should be noted that the investigative team received friendly cooperation throughout the entire investigation and appreciation for this help is acknowledged. A number of the recommendations for change evolved from the suggestions and the very real concern of EPA personnel for the improvement of their research program. The report bears on the condition of a research area which is the result of many forces and restraints. There is no intent to impugn the integrity or ability of any individual researcher, all of whom were found to exhibit professionalism and dedication to their program.

Finally, a most important point must be made which grows from but goes beyond the study. This report documents many cases of deficiencies in EPA research both past and present. It does not discuss many of the fine research efforts ongoing. The overriding purpose of this report then is to point the way to improving and enhancing the EPA research program, not to undermine the program. EPA can regulate wisely only if its decisions are based on information generated in a sound and comprehensive research program.

II. INTRODUCTION

A. BACKGROUND

The Environmental Protection Agency, in partial response to the mandate of Congress under the Clean Air Act, conducts research to study the adverse health effects of air pollution. A series of major air pollution/health effects studies were carried out between 1967 and 1975 and were considered by many experts to be the most comprehensive of their kind. This program attempted to implement a coordinated system of aerometric measurements, including measurements of sulfur dioxide (SO_2), particulates, total sulfate, carbon monoxide (CO), ozone, hydrocarbons, nitrogen dioxide (NO_2), and nitrate. In areas where these measurements were made, the EPA initiated concurrent epidemiological studies embracing acute and chronic respiratory illness, ventilatory function of children, and the aggravation of asthma symptoms. A portion of these studies eventually was given the formal title of "Community Health and Environmental Surveillance System" (CHESS).

Although data were gathered over the entire 1967–1975 period, the monograph, *Health Consequences of Sulfur Oxides, A Report from CHESS, 1970–71,* (EPA 650/1–74–004, May 1974), treats only some of these data. Some controversy exists in the professional community regarding the technical correctness of the results and conclusions as presented in that monograph. The controversy was intensified following a series of newspaper articles starting with a February 29, 1976 article in the Los Angeles *Times*. In this article, scientists both within and outside of EPA were reported to have alleged that the data and its analysis were manipulated to more strongly support certain regulatory positions taken by EPA.

Following these allegations, the House Science and Technology Committee and the House Interstate and Foreign Commerce Committee on April 9, 1976 held a joint hearing on the alleged mishandling of the CHESS program.[1]

While the hearing generally negated the idea of a planned manipulation of the data, many questions were raised as to the reliability of the data, the technical soundness of its analysis, and the subsequent validity of the conclusions reached.

Further, the EPA Administrator, Russell Train, testified that there existed a five-year program plan for sulfate air pollution and health effects R&D which would assure a sound data base for promulgating air quality standards in the future. However, the plan itself was not presented.

As a result of the questions raised by the April 9 hearings and other sources, the staff of the House Science and Technology Oversight

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[1] U.S. Congress. House. House Interstate and Foreign Commerce Committee and the House Science and Technology Committee. 94th Congress. 2d session. Report on Joint Hearings on the Conduct of the Environmental Protection Agency's "Community Health and Environmental Surveillance System" (CHESS) Studies. Washington. U.S. Govt. Print. Off. April 9, 1976. 25 pp.

Subcommittee and the Subcommittee on the Environment and the Atmosphere undertook a technical investigation of the entire CHESS program, with particular emphasis on the work reported in the 1974 CHESS Monograph. The investigation also looked into the follow-on CHAMP aerometric program and EPA plans for research to establish a sound technical basis for air pollutant health effects relationships. As noted in the Report on Joint Hearings cited earlier:

". . . the Committee on Science and Technology is currently investigating EPA's research program. This technical investigation will focus on CHESS and EPA programs planned to develop information necessary to make a decision on a sulfate standard." [2]

This investigation was launched due to the importance of EPA research to the Nation, not because of accusations raised in newspaper articles. It is simply that recognition of the importance of environmental research as a basis for regulation has and will continue to foster reviews of the EPA R&D program. We would like to emphasize that the team conducting this review worked with the goal of helping to improve EPA's research for the benefit of the country.

In planning the investigation, the team formulated the following 13 questions as a means of setting the scope and direction to the investigation. The team did not expect necessarily to arrive at findings in a format that would explicitly answer the 13 questions in the form they were set down. The questions are as follows:

(1) Did the CHESS measurement system utilize the best available instrumentation and sound operational protocols and quality control procedures?

(2) Were the precision and accuracy of the CHESS aerometric data sufficient to quantify pollutant exposure differences between communities where health effects were studied?

(3) Were the aerometric data consistent with and accurately representative of the exposures to pollutants received by the populations used in the health effects studies?

(4) Were new knowledge, instruments, and procedures introduced into the program as they became available and proven?

(5) Were the epidemiological populations adequately selected?

(6) Were the health measurement endpoints meaningful and reliable?

(7) Were the data reduction and analysis accurately and correctly carried out?

(8) What factors have retarded the analysis and reporting of the CHESS data?

(9) Did the health and monitoring data establish unambiguously what concentrations of specific pollutants are associated with measureable adverse health effect?

(10) If so, do the quantitative dose-response estimates in the CHESS report have a firm empirical basis?

(11) Were the conclusions drawn from the CHESS program sufficiently clear and unambiguous so as to form a sound basis for future action?

(12) Does the new "CHAMP" [3] program provide a substantially improved mechanism to provide aerometric data to support future

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[2] U.S. Congress. House Interstate and Foreign Commerce Committee and House Science and Technology Committee. Report on Joint Hearings. op. cit. p. 25.

[3] Community Health Air Monitoring Program, a systematic program for monitoring air pollution in connection with health effects studies.

epidemiological research and is an epidemiological research program planned to complement future aerometric monitorings?

(13) What additional steps, if any, should EPA take to insure that a sound technical basis will be available for future agency decisions pertaining to SO_2/sulfates?

Answers to these 13 questions were developed from the specific findings and are given at the end of Chapter III, Findings, Conclusions and Recommendations.

The investigative team consisted of at least one person with technical knowledge in each of the scientific disciplines expressly involved in CHESS, i.e., epidemiology, aerometric measurement, meteorology, data analysis, and R&D planning and management.

The first phase of the investigation involved visiting field data centers and measurement stations and interviewing the personnel who ran monitoring systems and who collected health data. The next phase involved a review of data and analysis procedures used in the CHESS monograph and intensive interviews with the key scientific and management personnel at the EPA laboratories at Research Triangle Park, North Carolina. The third phase consisted of interviews with EPA headquarters personnel who had been involved in the CHESS and CHAMP programs.

This report documents the investigation which was focused on the CHESS program and its published output. It was not, however, restricted to the CHESS program. The investigators looked into related programs (e.g. current epidemiology projects), and into supporting programs (e.g. development of measurement methods). As a result, the scope of the report is broader than CHESS. Since the CHESS program ended a year ago this report will have most value if it is pertinent to existing and future EPA research. It is definitely believed that many of the CHESS findings and recommendations are indeed relevant to current research programs in EPA, and that the CHESS mistakes might well be repeated if they are not documented. An Executive Summary is provided at the beginning of this Report for the convenience of the Committee in quickly getting an overall picture of the findings. The body of the report presents summarized findings and recommendations (Chapter III), followed by a detailed discussion and critique of the aerometric measurement and epidemiological parts of the CHESS program.

The field review naturally divided into air quality measurements and epidemiological studies. The first part of the field review (Chapter IV) presents the results of the evaluation of aerometric measurements, including the next generation CHAMP program. Chapter V presents an overview of the air quality analysis procedures, Chapter VI presents an analysis of the health effects studies. Appendix A presents a recapitulation of the aerometric and meteorological findings of the investigation as they relate to specific health studies. Appendix B presents a legislative history relative to the CHESS program.

B. HISTORY OF AIR POLLUTION HEALTH EFFECTS STUDIES LEADING TO CHESS OBJECTIVES

There has never been any question about the need for control of severe air pollution. Undisputed historical data have clearly implicated high levels of industrial pollutants, which invariably include oxides of sulfur and particulate matter, with increased incidences of health effects—both moribidity and mortality. These historical reports clearly indicated the danger from such incidents and pointed the way toward a need for additional information on the nature and extent of the damage which such pollutants might produce.

In early December, 1930, a thick fog covered the industrial Meuse Valley in Belgium. Firket[4] recounted that several hundreds were sickened by suddenly appearing respiratory symptoms, complicated in a large number by grave circulatory failure. He notes that, "More than sixty died on the 4th and 5th of December after only a few hours' of sickness. A sizeable number of livestock had to be slaughtered." Having calculated that mortality rates were ten and one half times average during this period, Firket commented that, should a similar fog afflict London, "one would have 3,179 immediate deaths to mourn." His words were prophetic. Four thousand excess deaths were attributed to the four day London Fog of December, 1952, and Logan[5] added the following historical note to his mortality figures:

"The incident was a catastrophe of the first magnitude in which, for a few days, death rates attained a level that has been exceeded only rarely during the past hundred years—for example, at the height of the cholera epidemic of 1854 and of the influenza epidemic of 1918–19." Nor was the United States spared. Nearly half (42.7%) the inhabitants of Donora, Pennsylvania experienced symptoms during the "smog episode" of October, 1948, and twenty died during the final week of October, a period which normally occasions but two or three deaths.[6]

A statistically significant increase in mortality was also documented during a "pollution incident" in New York City in November, 1953.[7] Thus, "air pollution," or "smog," or "fog" was recognized as a lethal menace, both in the United States and abroad.

These tragic episodes raised many questions and spawned a generation of research. Although various products of sulfur combustion were considered likely noxious agents in these episodes, the commentators were duly cautious in suggesting which pollutant or combination of pollutants might prove harmful. Recent reviews[8 9 10] describe population studies, clinical experiments, and toxicological studies designed to define which pollutant(s) pose risk, and a concommitant body of research sought to develop and refine techniques of pollution measurement.

The above chronicled incidents and research logically led to the question: If high levels of pollution can kill, what can low levels do to susceptible subpopulations, such as asthmatics, and what harm might come to the general population if exposed to low levels of pollution for years? To answer such questions, epidemiologists began to measure sublethal effects of pollution such as eye irritation, susceptibility to chest colds, subtle changes in pulmonary function, and asthma attack frequency (see references [11] and [12].) The Community Health and Environmental Surveillance System (CHESS) represented a natural extension of efforts to gather concurrent morbidity and air pollution data. In 1970, a description of CHESS [13] stated:

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[4] Firket, M., *Bulletin de L'Academie Royale de Medecine de Belgique* Series 5, Volume 11, Number 10 (1931), pp. 683–739.

[5] Logan, W.P.D., "Mortality in the London Fog Incident." *Lancet* Volume 264, Number 6755 (1953), pp. 336–338.

[6] Shrenk, H. H., Heimann, H., Clayton, G. D., Gafafer, W. M., Wexler, H., "Air Pollution in Donora, Pennsylvania: Epidemiology of the Unusual Smog Episode of October 1948". Public Health Bulletin Number 306 (1949).

[7] Greenberg, L., Jaconqs, M. B., Drolette, B. M., Field, F., Braverman, M. M., "Report of an Air Pollution Incident in New York City, November 1953." Public Health Reports Volume 77, Number 1 (1962), pp. 7–16.

[8] Rall, D.R., "Review of the Health Effects of Sulfur Oxides." Environmental Health Perspectives Volume 8 (1974), pp. 97–121.

[9] "Air Quality and Stationary Source Emission Control." National Academy of Sciences Report for the Committee of Public Works, United States Senate Pursuant to S. Res. 135 Serial #94-4 (March 1975), pp. 88–169.

[10] "A Critical Evaluation of Current Research Regarding Health Criteria for Sulfur Oxides." Technical Report prepared for Federal Energy Administration by Tabershaw/Cooper Associates, Inc. (April 11, 1975.)

> The keystone of the CHESS program is the coupling of sensitive health indicators to comprehensive environmental monitoring . . . .
>
> . . . EPA health research needs are practical and problem oriented. CHESS research is thus pragmatic and our goals are threefold: (1) to evaluate existing environmental standards: (2) to quantitate pollutant burdens in exposed populations; and (3) to quantitate health benefits of pollutant control.

It was perhaps this last goal which led to the rapid expansion of the CHESS system in 1968–70 and which necessitated the use of health measurements and monitoring methods which in some instances had not been adequately field-tested. Municipal regulation of industrial and power combustion, space heating, and incineration resulted in dramatic decreases in sulfur dioxide and total suspended particulates in New York City, Chicago, and elsewhere.[14] These favorable pollution trends were already evident in 1967. Thus, by 1970, it was urgent that population studies begin immediately if corresponding improvements in health indices were to be documented. CHESS data was gathered in New York City, Salt Lake City, Birmingham, Charlotte, and in Chattanooga from 1970 through 1975 and Los Angeles between 1972 and 1975. The analysis of the data and compiling of conclusions was begun aggressively as data became available. The facts relating to this program history are discussed in the following chapters.

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[11] Nelson, D.J., Shy, C.M., English, T., Sharp, C.R., Andleman, R., Truppi, L., Van Bruggen, J., "Family Surveys of Irritation Symptoms During Acute Air Pollution Exposures." Journal of the Air Pollution Control Association Volume 23, Number 2 (1973), pp. 81–90.

[12] U.S. Environmental Protection Agency. Health Consequences of Sulfur Oxides: A Report From CHESS,1970–1971. May 1974. EPA-650/1-74-004.

[13] Riggan, W. B., Hammer, D. I., Finklea, J. F., Hasselblad, V. Sharp, C. R., Burton, R. M., Shy, C. M., "CHESS, a Community Health and Environmental Surveillance System." Proc. of the Sixth Berkeley Symposium on Mathematical Statistics and Probability (1970).

[14] U.S. EPA. CHESS. op. cit.

III. FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

A. GENERAL FINDINGS

The findings resulting from the CHESS program review have extended into EPA's evolving task of developing a sulfate standard as well as a general perspective on EPA's entire air pollution-health effects research program.

The EPA five year plan for sulfates research cannot be commented on at this time because the plan is still in the formative stage. Thus, the recommendations deal primarily with what it is believed can be accomplished to prevent repetition of the problems produced by or related to the CHESS program.

The EPA CHESS program intended, as one of its prime goals, to provide a sound basis for relating human health effects to precise quantities of SO_2 and other oxides of sulfur in air and to provide a reliable record of the improvement of the health of the U.S. population as air pollution was controlled and reduced. The program, spanning 6 to 7 years, was to achieve these objectives by measuring and analyzing 6 health indicators together with SO_2, NO_2, suspended sulfates, total particulates, and oxidants in the air in 6 representative areas throughout the country. Only the 1969–1971 data were analyzed, correlated and published by 1974 in the CHESS Monograph. Most of the remainder of the data are in various states of analysis.

A critical review of the epidemiological and air monitoring programs with conclusions for each subprogram is presented in the body of the report. The results present a picture of a program pressured by EPA management-imposed time constraints to meet legislated mandates for promulgating new standards, hampered by inadequate mechanisms to detect and correct technical problems, and handicapped by budgetary and management restrictions placed on the program after it was well underway.

In the drive for results, the program did not adhere to standards of quality control, validation of methods, cross-checking of data, and calibration of instruments required in such research. The decision not to submit all results of on-going research for publication in professional journals deprived the CHESS program of an important source of peer review and evaluation at various stages, although the Monograph was sent to many reviewers for comments. The simultaneous publication of a large number of complex studies in a single report—the 1974 CHESS Monograph—rather than as individual on-going research reports may have been an administratively expedient method of publishing and collating results, but it undoubtedly reduced the effectiveness of peer review. The complexity of the document also impeded the public from acquiring an understanding of the results of the studies associated with policies of national importance.

As noted in Chapters II and V, the investigative team is aware that historic incidents and other clinical, toxicological, and specific epidemiological studies support the general concept that health and welfare will be improved as air pollution is reduced. However, technical errors in measurement, unresolved problems in statistical analysis, and inconsistency in data in the 1974 CHESS Monograph render it useless for determining what precise levels of specific pollutants represent a health hazard. Nonetheless, the CHESS Monograph presents some evidence of adverse health effects of air pollution, and, in particular, slightly increased prevalence of chronic respiratory disease is found in association with whatever levels of SO_2 and indeterminate particulate pollution were present in the air during the period the CHESS health panels were active. CHESS also has historical merit for undertaking the first massive air pollution health effects research program in the Western World. It is important to record and remember the lessons learned for future undertakings.

As pointed out in Chapter VII, the findings regarding CHESS epidemiological work corroborate the issues raised in previous reviews. This report collects the issues and goes into depth as to effects of errors, etc., and suggested corrective action.

In addition, this review documents serious errors and omissions in the aerometric data and analysis meteorology. Some of the more important specific findings and related recommendations related to the CHESS program are presented below, followed by RTP research lab operational issues, by suggestions as to possible improvements in health effects programs, and finally, by a review of the 13 questions set forth at the beginning of the investigation.

It should be noted that these findings do not contradict the conclusions in the report of the April 9 joint hearings.

B. SPECIFIC FINDINGS AND RECOMMENDATIONS

1. The data and analysis in the 1974 CHESS Monograph do not provide a reliable, quantitative basis for relating SO_2 or sulfate levels in the air to adverse health effects.

The methods and instruments used had associated measurement errors (inaccuracies) such that the threshold curves ("hockey-stick curves") presented in the Monograph are without basis in fact. The indicated thresholds occurred at levels at which the measurement methods (as used) were not reliable. Specifically in the case of SO_2 measurements the method used had a threshold of $25\mu/m^3$ and the accumulative errors found in hindsight in handling, shipping, and reading the instruments made SO_2 reading between 50 and $200\mu/m^3$ unuseable. There were similar problems with other measurements as pointed out in Chapters IV and VI.

2. The CHESS program did appear to demonstrate adverse health effects in association with local air pollution of undefined level and pollutant mix. Studies of chronic respiratory disease prevalence rates provided the most consistent results. These results are not translatable to communities other than those measured (an objective of the research) because the error uncertainties in the aerometric data made it impossible to arrive at reliable quantitative relationships.

3. The CHESS monograph has been referred to either directly or indirectly as a document supportive of regulatory and standards ac-

tions. Specific examples were found such as its use to support EPA positions on air pollution health effects in the following excerpt from the Administrator's Report to Congress for 1974:

> The CHESS studies *have demonstrated* [emphasis added] the benefits from improved air quality with respect to the chronic respiratory disease experience of subjects who have moved to communities having cleaner air. Also, the studies *have shown* [emphasis added] that children living for 3 or more years in communities having high level of air pollution have more acute respiratory disease episodes than recent immigrants to the community. . . . Data obtained from the CHESS program indicate that adverse health effects *are consistently* [emphasis added] associated with exposure to suspended sulfates, indeed, more so than to SO_2 or total suspended particulates. This information has initiated further study in the transport processes and control techniques for suspended sulfates.[1]

The CHESS study results were cited in an EPA document [2] dated May 1976. The preface of that document states "The report's objective is to review results of research by and under the sponsorship of ERC/RTP, related to criteria and hazardous pollutants since publication of the criteria and background documents." CHESS studies are explicitly mentioned in the report (e.g., page 207, page 276) with no references. Pages 303 through 308 seem to describe the CHESS studies as reported in the CHESS Monograph, although *no reference to a document is given*. Curiously, reference numbers 244 through 252 are not found in the body of the text where they would be expected (between pages 301 and 308). Inspection of the references list at the end of the pertinent chapter shows that the "missing" references, numbers 244 through 252, refer to the CHESS Monograph. Thus, it appears that CHESS results are used without attribution, and thus without caveat.

Recommendations:

(*a*) EPA should immediately publish and distribute a formal announcement to the effect that the 1974 CHESS Monograph is at best a preliminary document reporting research of varying degrees of reliability and as such should be considered only as a beginning study of larger problems. The notice should further point out: (1) That many of the problems leading to the unreliability of the research are not reported in the Monograph; (2) That no interpretations should be made based only on the data in the Monograph; And (3) that other data available at EPA, including data taken since the publication of the Monograph, indicate the need for reexamination of the conclusions in the Monograph. The notice should also announce the availability of and describe how to acquire the addendum recommended below.

(*b*) EPA should not utilize the 1974 CHESS Monograph as a source for specific quantitative data supportive of standards or regulatory decisions without explicit qualification.

(*c*) EPA should publish an addendum to the CHESS Monograph containing at least the materials in Chapters IV, V, and VI and Appendix A of this report. EPA should take the initiative to make sure this addendum is available to the public and included in all future issues of the Monograph.

4. If the EPA had drawn adequate attention to the many difficulties being encountered in the CHESS program (which was under pressure to provide data as fast as possible to support air quality standards

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[1] U.S. Environmental Protection Agency. Report to Congress. Progress in the Prevention and Control of Air Pollution in 1974 (undated) p. 39.

[2] Scientific and Technical Data Base for Criteria and Hazardous Pollutants 1975 ERC/RTP Review. Health Effects Research Laboratory, U.S. E.P.A. (EPA-600/1-76-023) May 1976.

under conditions set by the Congress, and on which OMB subsequently placed restrictions as to the allocation of positions and funds) it is possible that the program could have been either terminated with considerable savings or restricted in scope to permit a more satisfactory research program to be completed.

Recommendations:

(*a*) Legislation affecting the research responsibilities of the EPA should be reexamined to insure that unrealistic procedures and schedules are not assigned.

(*b*) Research programs should be designed to gain information and answer questions, not to support positions.

(*c*) If public policy requires expeditious research, every effort should be made to insure that the OMB allows all necessary funding and personnel.

(*d*) In the event that budgetary restrictions evolve which will have an impact on the completion of major projects, the EPA Administrator should be required to advise the Congress of the potential for such impact. Consideration should be given to requiring the Administrator to provide an annual analysis to the Congress which estimates the probable impact of proposed budget changes on major projects such as the CHESS program.

5. At the present time, OMB has the power to control the most detailed aspects in a research program. For example, a delay in the approval by OMB of health effects questionnaires submitted by EPA prevents or significantly delays the continuation of epidemiological studies associated with the establishment of air quality standards. Thus EPA has the responsibility for its mission, but lacks the necessary authority to carry it out.

Recommendation:

The OMB should be asked to develop procedures by which questionnaires and similar documents required for research programs can be given prompt review and approved without restrictive time limits for research programs of like nature.

6. The Health Effects Research Laboratory at Research Triangle Park is currently proceeding with the processing of the remaining data from the CHESS program. If adequate resources are made available to complete both current and past data processing programs, then the CHESS data may provide some additional insight into pollution health relationships or at least identify pitfalls to avoid in future studies. The loss of some key personnel involved in the CHESS program makes unavailable important insights provided by individuals who were involved in gathering of the data.

Recommendations:

(*a*) In view of the current unsettled conditions at the Health Effects Laboratory and the severe restrictions on manpower and budget, it is recommended that the unanalyzed epidemiological and aerometric data be examined critically by year (to determine at what point improvements in measurement make the data acceptable) and that analysis be carried out only on that data that appears to have a higher degree of validity than the '69–'71 data used as a basis of the 1974 CHESS Monograph.

(*b*) Steps should be taken to attempt to publish research in traditional, referred, archival journals in a timely fashion.

(*c*) The results of large or complex projects should not be published solely in monograph form. If EPA decides to publish such results in monographs as well as journals, then EPA should take care that, within the limits of reason, all pertinent data are included.

(*d*) Projects should not be initiated unless there is full assurance that the data collected in such projects can be properly analyzed and reports prepared in a realistic time frame for policy consideration. If policy considerations dictate a time frame, then research staff must have a part in deciding what can realistically be accomplished in the allotted time.

7. While CHAMP looks more promising for providing reliable real time measurements of air quality (absolute pollutant levels), the system reliability and precision for SO_2, sulfates, and NO_2 have yet to be proven.

Recommendations:

(*a*) The aerometric and quality control programs in EPA should be further strengthened and improved.

(*b*) Every effort should be made to shorten the time between the acquisition of data and quality assurance analysis of data so that errors in instrumentation and collection may be corrected.

(*c*) The practice of employing development stage instruments in field operations before qualification testing is satisfactorily completed should be stopped.

(*d*) Field utilization of laboratory models of instruments is not acceptable until the instrument has been thoroughly checked out in the field and until all field personnel have been adequately trained in its use.

(*e*) The opening of the CHAMP operation contract to competition now, before development is complete should be reexamined by EPA policy management to see whether the merits of open bidding at this time outweigh the problems of instability.

(*f*) Health effects research personnel need to coordinate closely with air quality and monitoring personnel so that there is early understanding as to the chemical species to be monitored as well as the accuracy needed for support of health effects research.

8. Meteorological support to the epidemiological program has been passive and not fully developed.

Recommendations:

Additional meteorological support is needed in the health research-air pollution effects studies. Assuming that CHAMP stations will continue in operation, the meteorological instrumentation should be uniform and complete for all stations.

9. The characterization of species of air pollutants and combinations thereof which are of particular health or welfare significance needs to be speeded up. The useful output from future large scale epidemiological studies of general air pollution effects will be minimized if such characterization is not available. Such characterization will require a greater effort than is now possible with currently assigned resources. The present Federal effort in this area is fragmented and uncoordinated.

Recommendation:

The EPA Health Effects program as well as interagency utilization of all available Federal and extramural resources in the health effects area should be examined with the objective of significantly accelerating research in this area.

10. The overall impression left with the review group was a general awareness of many of the problems we found in the air quality health effects research area but an apathy to really drive to correct them quickly.

Recommendations:

(*a*) A truly interdisciplinary task force led by an eminent scientist should draw up a program plan for EPA to develop a solid base of knowledge and procedures in aerometric instrumentation and measurements, meteorology, field data gathering, quality control, epidemiology project design and testing and panel planning.

The plan should be thoroughly reviewed with peer groups and then funded for two years or as required at the expense of other programs so that effective tools for meeting research needs will be available for future programs.

(*b*) At the very least, CHAMP should be pushed to verify present instruments and protocols so that reliable data at pollutant concentrations within instrument capabilities can be achieved. New third generation instruments, such as the pulsed fluorescence devices should be developed and proven for field usage so that reliable values with uncertainties of less than ±20% can be detected for pollutants at concentrations well below current standards.

(*c*) The epidemiological questionnaires, panel selection criteria and other items criticized in this report should be worked out and approved by peer groups so that EPA will be prepared for the next round of serial or episodes investigations with reliable tools and plans. Specifically, questions such as the following must be resolved for future epidemiological studies:

(1) How do CRD[*] questionnaire responses change on serial administration in an area with unchanging pollution patterns?

(2) What is the sensitivity of the self-administered CRD questionnaire compared with its use in an interview?

(3) What is the nature of the statistical dependence of ARD[★] attack rates, and what formal statistical methods are appropriate to the analysis of relative attack rates?

(4) What can be done to tighten the eligibility requirements for asthma and cardiopulmonary panels?

(5) How can the statistical analysis of asthma and cardiopulmonary panels be improved?

(6) What combination of CHESS health measurements is most appropriate to long-term serial surveillance?

(7) What combination of CHESS health measurements is appropriate to intensive studies of specific pollution hazards?

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[*] CRD=chronic respiratory disease.
[★] ARD=acute respiratory disease.

(*d*) Along with correcting epidemiological program deficiencies pointed out in Chapter VI of the report, the following ideas were raised in team interviews with EPA personnel and others and are worthy of review in such a program as outlined above.

(1) Even though CHESS was stopped partially due to the cost of such massive programs, the CHESS concept of health surveillance should be reevaluated before a decision is made not to undertake similar programs in the future. Documentation of improving public health with pollution abatement; identification of new pollutants becoming threats; and baseline serial health data are important.

(2) The appropriateness of the CHESS endpoints (i.e., dependent variables) such as chronic respiratory disease (CRD), should be evaluated with respect to utilizing more objective and more easily quantified health measurements, such as mortality rates, admissions to emergency wards, or blood or pulmonary function tests as being easier to document and more reliable.

(3) Surveillance in small rural towns may yield valuable control data on serial health measurements.

(4) Epidemiological program planners should consider utilization of local physicians to help develop and screen panels and gather data in localities where there is an interest.

(5) Additional consideration should be given to the study of high risk groups such as those in nursing homes, those recently admitted to an intensive care unit for myocardial infarction, and premature infants.

(6) Resources should be available for opportunistic epidemiology to study interesting events, such as the January 1976 episode of high SO_2 in Magna, Utah. Such events as this may allow one to disentangle the acute effects of particular pollutants.

(7) Alternative populations should be considered, and cohort studies of particular occupational or medical risk groups may prove valuable.

(8) More attention might be given the need for individualized dosimetry.

(9) Under what circumstances, if any, can epidemiologic studies alone provide unambiguous dose-response data?

(10) More exotic studies might be considered. The health effects of a new event could be observed, such as the construction of a coal gasification plant. Changes in a town which is known to plan selective modifications in the regulation of a specific pollutant could be studied. Studying vacationers from small towns who spend a week in a polluted urban center might be considered. Longer term migrant studies might also be useful.

C. R&D Related Findings

During the course of this investigation the extensive interviews brought to light some issues which did not bear directly on the CHESS program above but which are important to the effectiveness of the total EPA R. & D. program. Generally the Research Triangle Park EPA Health Effects Research Laboratory, and in fact all RTP laboratories visited, appear to be inadequately staffed and suffering from poor morale due to a number of factors including frequent changes in leadership, poorly understood organizational changes, uncertainty about responsibilities, difficulty in recruiting high quality personnel for leadership positions, poorly defined long-range task objectives, and physical separation of working units. In addition, there appear to be serious problems of coordination and communication between divisions at RTP as well as at Headquarters, Washington.

These general findings are also borne out in the report on "The Organization and Management of EPA's Office of Research and Development" prepared by the Subcommittee on the Environment and the Atmosphere of the House Committee on Science and Technology in June, 1976.[3]

There follow several specific findings and related recommendations.

11. The laboratories have not yet completely recovered from the (inevitable) disruption associated with the December, 1975 reorganization of the Office of Research and Development.

Recommendation:

Since stability is an important ingredient in any good research organization, the Center should be allowed to function in its present mode without further significant reorganization until the end of Fiscal Year 1977 with all possible help it can use from Headquarters.

12. There is evidence of a need for improved coordination between the four research laboratories at the Environmental Research Center, RTP, particularly between the Health Effects Research Laboratory and the Environmental Monitoring and Support laboratory. The exchange of data and coordination of effort among the EPA/RTP laboratories, and between EPA, contractors, and Federal laboratories involved in similar programs is wholly inadequate.

A specific example of this lack of coordination is seen in CHESS. However, even after this learning experience the Environmental Protection Agency is still not well organized to undertake and conduct multidisciplinary field projects and, in fact, certain of the recent organizational changes are believed to have exacerbated this problem. When multi-disciplinary projects are organized and run by staff having a single, particular discipline, important elements of the problem may be omitted or given insufficient attention. Objectives need to be correlated more effectively with requirements and capabilities. Statisticians and quality control experts need to play a larger role in the planning of such projects. Problems of coordination and communication seem to arise at project levels because of the Office of Research and Development organizational structure in which individual laboratories report directly to separate management offices in EPA Headquarters. This is epitomized in the draft research plan for sulfates, for example, wherein the research effort is divided into four distinct segments at RTP but there is no program management at RTP to insure coordination. As a result, the four research elements are not developed on consistent premises.

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[3] U.S. Congress, House Committee on Science and Technology, Subcommittee on the Environment and the Atmosphere, Organization and Management of EPA's Office of Research and Development, 94th Congress, 2nd Session, June 1976. U.S. Government Printing Office, Washington, D.C. Serial LL, 40 pp.

Recommendation:

(a) In accordance with the recommendation under 11, above, improved coordination should be sought at this time without formal organizational changes. This could be achieved through establishment of an authoritative peer review panel to monitor all on-going projects and insure appropriate interface between the various disciplines. Such a review panel should represent the highest level of research skill and should assist not only in program planning and review for scientific objectivity, but in peer review of major scientific reports with policy implications. Such review should insure that future reports are released in a timely fashion after complete scientific assessment.

This need for coordination cannot be satisfactorily achieved by *ad hoc* arrangements alone. Nevertheless, the formation of *ad hoc* working groups, under the oversight of the continuing peer review panel mentioned above, could be a useful mechanism for attacking special problems, such as planning a coherent sulfate research program.

In addition, the following additional steps might be taken without affecting the stability of the laboratory:

(b) A stronger focus on management at the Environmental Research Center, RTP, would aid in interfacing with the four Deputy Assistant Administrator Offices at Washington to prevent separate tasking on essentially identical problems.

(c) Consideration should be given to creation of a systems analysis/operations research program review group at Headquarters of EPA and perhaps at each technical center. This activity could insure that proper attention is addressed to all scientific disciplines in program plans and budgets, irrespective of which scientific discipline initiates a program. This group might act as staff to the peer review panel.

(d) The Science Advisory Board's (SAB) charter should be reexamined to improve the assistance rendered to the Health Effects Research Laboratory and to Washington project directors. The SAB should have direct informal access to the research programs and opportunity to review and recommend actions relative to planning and coordination of projects involving several divisions. The SAB should have scientific review responsibility for programs, and its participation should not be limited to public evaluations after something goes wrong.

13. The EPA research programs in many cases were found to be somewhat isolated. The research staff does not seem to avail itself of a maximal technical exchange with scientific peers. It seems that to a large extent outside contracts go to the same groups again and again.

Recommendations:

(a) EPA should actively seek cooperative research programs with a variety of universities, other laboratories, other agencies. *NOTE:* This is not a recommendation that more task-limited contracts be given, but that truly cooperative programs be implemented in which the outside laboratory can contribute its own ideas.

(b) EPA should arrange for research staff to spend six to eighteen month assignments working at other labs to reduce scientific isolation and to promote career development (see below). Similarly, they should promote reciprocal visiting research assignments for outside scientists to work at EPA laboratories.

(c) EPA should consider funding individual, worthwhile Ph. D. thesis research as a means of broadening their technical community.

(d) The Science Advisory Board should be asked to help in developing such outreach programs.

14. There are examples of increasing overlap among the Office of Research and Development (ORD), the Office of Pesticides (OP), and the Office of Toxic Substances (OTS), at Washington, in assignments to the Environmental Research Center, RTP. Instances were noted where both ORD and OTS have asked the RTP Center for research on the same substances and where it was evident that neither the divisions at the RTP Center nor the Offices at Washington had coordinated the inputs to the Center during the development and assignment of projects.

In addition it appears that research is being carried out in offices other than ORD.

Recommendation:

The Administrator should clarify the role of the Office of Research and Development in managing Agency research, and the role of the laboratories in carrying it out.

15. The various EPA groups at RTP are now scattered geographically in such a way that the peer interaction needed to insure proper coordination and exchange of ideas is physically difficult.

Recommendation:

Whatever final management concepts evolve, this separation of facilities must be resolved in an expeditious fashion if the EPA program at RTP is expected to function with any degree of cohesiveness.

16. Poor staff morale seemed largely due to the superposition of a very difficult task (research in support of EPA's regulatory mission) upon a very uncertain and fragile system for the support of research. This would seem to cause or at least contribute to anxiety among the professional research staff, especially since there appears to be no plan of career development for this staff.

Recommendation:

EPA management should develop, implement, and defend a professional career development plan for each professional employee and for the staff as a whole. Developing such a plan will contribute to better management by forcing a comparison of goals and resources. An employee secure in a peer-respected professional career will more happily tolerate the exigencies of research in a regulatory agency. Management of the ORD will sometimes have to defend its commitment to such a plan against regulatory demands.

17. As stated above, major improvements in research execution are needed. If, after the end of fiscal year 1977, the present structure is judged inadequate to achieve this, a number of alternatives and factors should be considered. The RTP laboratory directors are divided as to the type of management structure needed but there is a general impression that the National Environmental Research Center

(NERC) concept was preferred to the four-RTP-division/four Washington-manager structure which currently exists.[4] A major problem is the lack of a single manager's office at the Center to insure interdivisional review of multi-disciplinary projects and to secure input from all divisions on such projects.

If success in recruiting key leadership and improving program execution cannot be shown, even more fundamental steps may be needed.

The steps to be considered might include (1) moving the existing EPA research program into a new or existing agency; (2) establishing a new agency to provide the basic, long-term research support needed (but not being done) and effectively dedicating the present EPA laboratories to short-leash support of the agency regulatory programs; (3) assigning long-term research support responsibilities to other existing agencies.

Recommendation:

The Administrator must be prepared to answer hard and fundamental questions such as, should EPA conduct research?

D. Recapitulation of Guiding Questions

The following tabulation provides summary answers based on the findings of the investigative team to the guiding questions formulated at the beginning of the investigation.

(1) *Did the CHESS measurement system utilize the best available instrumentation and sound operational protocols and quality control procedures?*

The instrumentation was that of the state of the art at the time the program started. However, it is quite clear that neither the protocols nor quality control procedures were adequate to accomplish the objectives of the program, and that the data usefulness could have been greatly enhanced if well-known quality control procedures had been rigorously followed. For example, if the procedures described in the CHESS Monograph (but not actually used) had been implemented, the data would have been much more useful. If error bars had been associated with each data point the weakness of some of the cause-and-effect relationships might have been evident. This, in turn, would probably have prevented some of the over-interpretation of data.

(2) *Were the precision and accuracy of the CHESS aerometric data sufficient to quantify pollutant exposure differences between communities where health effects were studied?*

For many pairs of communities the answer is clearly no—both because of inadequate procedures and also because at apparent concentration levels in the lower-concentration areas the measurement methods were incapable of detecting differences or changes in those pollution concentrations.

(3) *Were the aerometric data consistent with and accurately representative of the exposures to pollutants received by the populations used in the health effects studies?*

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[4] Under the NERC structure, the entire RTP laboratory reported to a NERC Director who in turn reported to Washington Headquarters.

This question cannot be answered, because there is no information in CHESS on the relation between individual exposure and ambient air quality. Thus, the CHESS researchers did not know this answer either. In addition, the practice of having only one aerometry station per community made it difficult to assess area-wide concentrations. This illustrates the importance of personal dosimeters.

(4) *Were new knowledge, instruments, and procedures introduced into the program as they became available and proven?*

It seems the introduction of new techniques was slow at best. For example, as stated above even well-known quality control procedures were introduced only slowly. The Committee understands the importance of consistency in a project like CHESS, but this can be assured with proper quality control techniques.

(5) *Were the epidemiological populations adequately selected?*

The findings raise doubts as to the validity of certain of the population selections.

(6) *Were the health measurement endpoints meaningful and reliable?*

Again, the findings disclosed many shortcomings in this area. As with the areometry, the health measurements could have been more useful if validated, etc.

(7) *Were the data reduction and analysis accurately and correctly carried out?*

There were instances of errors in both data reduction and analysis.

(8) *What factors have retarded the analysis and reporting of the CHESS data?*

Several factors were uncovered. The most important appear to be the forced change of computer and support contractors.

(9) *Did the health and monitoring data establish unambiguously what concentrations of specific pollutants are associated with measurable adverse health effects?*

The findings clearly say no.

(10) *If so, do the quantitative dose-response estimates in the CHESS report have a firm empirical basis?*

From (9) the answer must be no.

(11) *Were the conclusions drawn from the CHESS program sufficiently clear and unambiguous so as to form a sound basis for future action?*

Again, the answer is no. CHESS does indicate the need for a rigorous program of health effects research.

(12) *Does the new CHAMP program provide a substantially improved mechanism to provide aerometric data to support future epidemiological research and is an epidemiological research program planned to complement future aerometric monitorings?*

The CHAMP system is clearly an improvement in aerometric pollution measurement, although it is not yet fully validated. There is no clearly defined, well-targeted, coordinated epidemiological program to make use of CHAMP at this time. There are no projects in epidemiology making use of CHAMP data.

(13) *What additional steps, if any, should EPA take to insure that a sound technical basis will be available for future agency decisions pertaining to SO_2/sulfates?*

For the answer to this question, refer to all the recommendations in the sections B and C concerned with program improvements.

E. CLOSING REMARKS

The investigative team is aware that this is a very critical report. The Environmental Protection Agency is a relatively new agency which has been confronted with the need to grow rapidly and to assume a large burden of responsibility. The enforcement of these responsibilities has increased in political significance with the growth in intensity of the overall energy problem. All EPA personnel consulted in this study were generally cooperative and hopeful of being able to provide constructive suggestions. Indeed, the recommendations presented here are, in many instances, suggestions and comments made by EPA personnel. It was not difficult to identify many deficiencies within the CHESS program or to relate these difficulties to the need for changes in organization and management within EPA. The difficult task will be to resolve these issues and construct a more effective organization to meet the very real problems of our society which have been mandated to the Environmental Protection Agency for resolution.

IV. CHESS AEROMETRIC MEASUREMENTS

A. Introduction

As pointed out in the introduction, the attainment of precise, reliable, reproducible, and real time air quality measurements in the field (e.g., SO_2 and particulates) was a critical element of the CHESS program. This chapter provides a critical review of the aerometric measurement aspects of CHESS.

However, before reporting on this review two facts about CHESS aerometry should be mentioned. First, the methods used in CHESS, especially in 1970–71, were probably as good as any available. Second, quality control procedures were slowly introduced into the CHESS program. EPA cannot be criticised, and is not criticised in this report, for using the best available methods. However, EPA can be criticized for not pursuing a vigorous program of quality control throughout CHESS. The review reported here showed that CHESS did not employ well-established quality control measures. The quality control program described in Appendix A of the Monograph was not carried out. A thorough quality control program would have discovered, for example, the temperature effects on the method used to measure SO_2 (described below). It would also have placed bounds on the validity of the data and precluded overinterpretations.

In the design and implementation of any measurement system, the single most important consideration is the end user of the data produced by that measurement system. In the simplest of all measurement processes, an individual scientist conducting his own research, both measures the parameters of interest and uses the resultant data to draw conclusions about his experiment. In such a process the individual involved has at his disposal all of the information contained in the data, especially that concerned with the limitations of the data and the constraints under which they should be used. In this type of situation, few formal qualifications of the recorded data are necessary since those qualifications are implicit in the mind of the scientist.

In larger programs however, the measurement process and the utilization process are quite often compartmentalized such that one group of scientists is responsible for the collection, quality assessment and storage of the measurement data, and a second, usually nonrelated, group of scientists is responsible for the synthesis of all pertinent information into a final set of conclusions. In this type of systems research, the determination of the fundamental quality of the measurement data and transmittance of that quality assessment are the single most important qualifier in the process of going from observation to understanding.

The CHESS program, as designed and implemented by the Environmental Protection Agency, is a classic example of the large systems approach to research. The epidemiological measurements were designed, conducted, and stored by one group of scientists; the aerometric measurements were designed, conducted and stored by a second group of scientists. The desired end product, a correlation of health effects with atmospheric pollution was then derived from these two independent sets of data accumulated in a large data storage network. It is important to reemphasize here that in such a research program it is incumbent upon the measurement personnel to transmit to the data user all of the information contained in the resultant data, especially that relative to accuracy and precision. In order to understand the problems encountered in a large research program such as CHESS, it is necessary to understand the types of measurements that were made.

The assessment of atmospheric pollution exposure received by a defined population can be derived from one of two broad classes of measurement. The first is a measurement that yields an "index" of pollution. The second is a measurement that yields quantitative information about a specific pollutant as it is found in the atmosphere.

A pollution index is a measure of the relative level of pollution which contains little or no information as to the specific chemical or physical properties of that pollution.* These indices can be useful in assessing short-term trends of atmospheric quality in well-defined and limited geographic regions. They cannot be used to deduce information about the source or chemical nature of the material being measured. They also cannot be used to assess long-term trends of pollution burden since gradual changes in pollution sources will distort the quantitative aspect of the index. Most importantly, they cannot be used to correlate atmospheric pollutant levels among diverse geographic areas. Here again, the difference in chemical and physical makeup of the pollutants being measured distort the quantitative aspect of the index.

An example of a measurement that gives a pollution index is the dustfall observations as applied in CHESS. In this method, an open topped cylinder called a dustfall bucket is used to collect any particulate matter that falls out of the atmosphere. This collection is carried out over a long time period, usually one month; and the total dry weight of material collected is used to estimate particulate burden of the atmosphere during that time period. A detailed description of this process is given later in this Chapter. This measurement falls in the index class because all solid material, regardless of its derivation or chemical nature, is included in the final quantitative result.

The second class of pollution measurement is that which contains information both on the specific species of pollutants and on the atmospheric concentrations of those pollutants. In this type or measurement the signal that is measured is derived from a process or property which is specific to the pollutant of interest and which correlates directly with the concentration of that pollutant in the atmosphere. An example of this type of method is the West-Gaeke procedure for the measurement of atmospheric sulfur dioxide. In this procedure, air is bubbled through an absorbing solution at a known rate. The solution is specific for the absorption of SO_2 from the air. After a known duration of sampling, the quantity of SO_2 which was absorbed from the air is quantitatively determined by the formation of a colored chemical complex of SO_2. If carefully carried out, the procedure gives an accurate value for the SO_2 concentration. The procedure is described in detail later in this Chapter.

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* N.B. This index is not the kind of "air quality index" often used popularly (in radio broadcasts, etc.) to advise citizens of the relative air quality of a city. Such popular air quality indices are usually arrived at by combining measurements of several pollutants.

Measurements such as the West-Gaeke procedure, which are specific and quantitative, can be used to compare atmospheric pollutant burdens across diverse geographic areas and through long time periods. They can also be used to assess short-term variations in pollutant levels provided that sufficient sensitivity exists in the method to obtain a meaningful signal for the short time period used. In conducting a program such as CHESS, where an attempt is made to relate health effects to pollution burdens, only those measurements that fall in the second class, specific and quantitative, can properly be used to assess the relation between health effects and pollutant burden.

In this chapter, an attempt will be made to evaluate the methodology used to measure aerometric parameters and to assess the validity of the resultant data. The review will encompass procedures used in the field situation, the quality control exercised over the procedures, and the data storage and retrieval network. Conclusions will be drawn as to the adequacy of the measured pollution levels to assess exposures received by specific CHESS population groups.

B. Review of Chemical and Physical Methods

1. THE WEST-GAEKE METHOD FOR THE MEASUREMENT OF AMBIENT SO_2

a. Description of the Method

The West-Gaeke colorimetric procedure for SO_2 determination is the designated Reference Method (Federal Register, *36*, No. 84, 6168, April 30, 1971).* Atmospheric SO_2 is collected by bubbling air through a solution of potassium tetrachloromercurate (TCM). The product of the reaction between SO_2 and TCM is the nonvolatile dichlorosulfitomercurate that is then determined quantitatively by reaction with formaldehyde and pararosaniline hydrochloride, followed by photometric measurement of the resulting intensely colored pararosaniline methyl sulfonic acid.

b. Description of the Field Apparatus and Sample Collection

Outside air is drawn through a sample line at the rate of 200 ml min^{-1}, then through a 6-inch long glass bubbler stem (tip diameter of 0.025 in.) immersed in 35 ml (50 ml after January, 1974) of 0.1 M TCM solution contained in a 32 mm diameter by 164 mm long polypropylene sample container. The exhaust air passed through a glass wool moisture trap, then through a hypodermic needle used as a critical orifice to control the flow, through another moisture trap, and finally through a vacuum pump. A sample consisted of a 24-hour collection. Collected samples were stoppered, and mailed to EPA/RTP for analysis.

c. Validity as a Laboratory Procedure

A collaborative study by McKee et al. (H. C. McKee, R. E. Childers, and O. Saenz, Southwest Research Institute, SWRI Project 21-2811, EPA contract CPA 70-40) indicates that "the method cannot detect a difference smaller than 10 percent between two observations by the same analyst in the range of 0 to 1000 $\mu g\ m^{-3}$. A difference of 20 percent or less may be detected above $300 \mu g\ m^{-3}$, and a difference of less than 50 percent may be detected above $100 \mu g\ m^{-3}$." For analyses conducted by different laboratories on the same sample, "the method cannot detect a difference of less than 20 percent between single-replicate observations of two laboratories in the range of 0 to 1000 $\mu g\ m^{-3}$. At a level of 100 $\mu g\ m^{-3}$, a difference of less than 100 percent is not detectable." The National Primary Ambient Air Quality Standard for SO_2 is: For 24 hour average, 365 $\mu g/m^3$. For annual average, 80 $\mu g/m^3$. Thus if the standard is met, most values will be around or below 80 $\mu g/m^3$, no more than one will be above 365 $\mu g/m^3$.

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*Alternately see CFR Title 40, Part 50, Appendix A.

Regarding the lower limit of detection, the authors cited above propose a value of 25 $\mu g\ m^{-3}$ as a practical figure. "A single determination less than this value is not significantly different from zero" (Instrumentation for Environmental Monitoring, Air-SO_2, Instrumentation, Lawrence Berkeley Laboratories, March 1972).

It is therefore evident that a single analysis is of little use, considering that the expected concentrations of SO_2 will usually be less than the ambient air quality standard of 80 $\mu g\ m^{-3}$. Results should be regarded as valid only in terms of the mean of multiple determinations, and only when the analytical method has been followed rigorously by experienced analysts.

2. TOTAL SUSPENDED PARTICULATES

Total suspended particulates (TSP) were measured using the EPA Reference Method as specified in the Federal Register (*36* (84): 8191–8194, April 30, 1971‡).

Total suspended particulates (TSP) were measured by drawing air through a prewieghed 8 x 10 inch glass fiber filter for a period of 24 hours. The apparatus used for this procedure was the standard High Volume Sampler. At the end of the 24 hour time period, the filter was reweighed, and the TSP computed on the basis of total air flow. The air flow rate was approximately 60 $ft^3 min^{-1}$ at the start, and must be not less than 40 $ft^3 min^{-1}$ at the end for the measurement to be acceptable. The average air flow rate was computed on the basis of a straight-line interpolation between beginning and ending flow rates.

The National Primary Ambient Air Quality Standard for TSP is: For 24 hour average, 260 $\mu g/m^3$. For annual geometric mean, 75 $\mu g/m^3$.

3. SUSPENDED SULFATE

Suspended sulfate was analyzed, during the CHESS program, using portions of the TSP samples. From the beginning of CHESS to September 1971 the turbidimetric method of analysis was used; then the turbidimetric method was dropped in favor of the methylthymol blue method, which was used throughout the remainder of the CHESS program.

The turbidimetric method consists of the water extraction of soluble sulfates on the TSP filter, the addition of a barium chloride preparation to the extract, and measurement of the resultant turbidity (from the formation of insoluble barium sulfate) with a spectrophotometer or colorimeter. Accuracy of the method is affected by the kind and concentration of other ions present, as well as pH, conductance, temperature, and barium concentration in the test solution.

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‡ Alternatively see CFR Title 40, Part 50, Appendix B.

The methylthymol blue method also utilizes the water extraction of soluble sulfates from the TSP. The filter extract is then passed through an ion-exchange bed to remove interfering ions, and barium chloride is added under slightly acid conditions, forming barium sulfate. Then the test mixture is made alkaline and methylthymol blue is added, which forms a chelate with the excess barium. The uncomplexed methythymol blue is equivalent to the amount of sulfate present, and is measured spectrophotometrically. The methylthymol blue procedure is automated (Technicon Autoanalyzer) in all steps following water extraction of the TSP, and this part of the procedure is reproducible within a range of 2 percent. Error in the determination of sulfate occurs predominantly in the steps preceding the methylthymol blue method.

4. DUSTFALL BUCKET, TAPE SAMPLER, CASCADE IMPACTOR, AND CYCLONE SAMPLER

In addition to TSP measurements using the Hi-Vol sampler, four other means of estimating particulate concentrations were used at various times. They are the dustfall bucket, the tape sampler, the cascade impactor, and the cyclone sampler.

(*a*) The name "dustfall bucket" is adequately descriptive. It is basically an open-topped cylinder, with some protection against wind and rain loss, that is left out in the open, close to the ground or on a rooftop, for a month. At the end of that time the dry matter collected is weighed, and sometimes analyzed for trace metals. The dustfall bucket method is very crude and misses almost completely the very significant part of the aerosol, including the respirable aerosol, that does not settle rapidly. It must be considered here, however, because dustfall measurements were extrapolated to obtain estimates of suspended sulfates and sulfur dioxide in New York City during the period 1949–58 ((Table 5.2.1, CHESS Monograph), and intermittently in Chicago (Table 4.1.A.3), CHESS Monograph). Dustfall measurements were used as the basis for these extrapolations because there was no other basis for such estimates, but it must be remembered that the relationship between suspended sulfates and dustfall is unknown, and that between sulfur dioxide and dustfall is another step removed from reality.

(*b*) Coefficient of Haze (COH) is determined by the automatically operating tape sampler. It is determined by measuring the optical density of an aerosol deposited on a filter tape. The aerosol deposit is obtained by drawing air at a given flow rate through white filter paper tape for a known period of time. If one could assume that the composition and physical characteristics of the aerosol in a given location did not change with time—that only atmospheric loadings would change—then the COH would give a fairly good approximation of the variations of particulate loading and visibility.

However, this assumption is seldom justified, and even at a given location the COH only roughly approximates the true particulate loading. The COH method is worthless, or nearly so, for comparisons between areas with dissimilar aerosols. For example, the aerosols collected at the Utah sites are primarily the light-colored aluminosilicate dust, whereas the aerosol collected within the inner core of large cities has a predominantly sooty character. For a given particulate loading the Utah aerosol will often have as little as one-tenth the optical density of the urban aerosol.

(*c*) The cascade impactor operates on the principle that particles in an air stream will tend to follow a straight line when the air stream is deflected, and thus can be impacted on a surface in their path. The cascade impactor consists of a series of parallel plates separated by precisely determined spaces. Alternate plates contain a certain number of holes of a size that is decreased as one goes through the series of plates from entrance to exit. Alternating with the plates containing the calibrated holes are plates without holes. These may be coated with a medium for the trapping of impinged particles. Air is drawn through the apparatus at a known rate, and the particles are collected in decreasing size fractions related to the decreasing size of the holes in the plates.

(*d*) The cyclone sampler is a device for the collection of the respirable size fraction of an atmospheric particulate loading. It operates on the principle that the inertia of individual particles will tend to keep the particles moving in a straight line when the air stream in which they are carried is deflected. By this means the larger size particles are removed by impaction and settling, while the respirable particles are carried along with the air stream and are subsequently collected on a filter.

C. Findings and Evaluations of Measurements and Data Reduction

It is important to preface this evaluation of the CHESS air monitoring program with a statement of the following facts. The investigative team looked backward at the program through a window in time with all of the subsequent knowledge built up during that time. More than ten years have passed since the initial planning of the CHESS program and more than six years have passed since the first data were collected. During that time there has been a vast improvement in the understanding of the methods used for pollution monitoring. Many of the procedures used in CHESS have subsequently been found to contain serious errors. These problems were often uncovered as a direct result of research and quality control programs ongoing within EPA. It would thus be unjustified to lay criticism on the principals in the CHESS program for using state of the art measurement technology.

On the other hand, some serious oversights in scientific judgement did occur. In the area of pollutant monitoring, these oversights could have been completely avoided had proper attention been paid to even rudimentary quality control procedures. Throughout the program, much more emphasis was placed on the uninterrupted collection of data than was placed on the systematic evaluation of data quality. The field investigation stage of this review identified numerous problems that resulted in the propagation of unnecessarily large errors in the aerometric data. These unevaluated errors persist even today in the data as it is stored in the CHESS computer system. They could have been avoided or easily discovered and quantified had a well-designed quality control procedure been applied to the CHESS aerometric monitoring program. This statement is contrary to the statement of the quality control procedures in appendix A of the 1974 CHESS Monograph. Appendix A was not a manual provided to CHESS data gatherers, but was written long after the data in the 1974 Monograph were collected. However, during the field investigation of the CHESS monitoring contractors, it was found that the quality control procedures as described in Appendix A of the CHESS Monograph were routinely disregarded. In fact, for the first two years of the program, virtually no EPA-directed quality control program was implemented at any of the New York, Salt Lake City or Los Angeles CHESS monitoring sites. Problems that were found in this time period were observed and documented by contractor personnel and it was mainly through their personal professional conduct that any of the field problems were corrected. Reasons for this rather gross oversight on proper data management can only be conjecture, but it did appear that inadequate staffing of the monitoring group, coupled with the intense pressure to get the monitoring stations on line and producing data, led to the situation described.

In fairness (regarding the time perspective mentioned earlier) the problem of inadequate quality control on many large EPA programs eventually was recognized internally and in 1974 a Quality Control Branch was established in the Quality Assurance and Environmental Monitoring Laboratory. This branch was given the authority to implement proper quality control procedures on all large atmospheric monitoring programs. Since the formation of this group, there has been a significant and steady improvement in quality assurance as applied to air monitoring methods and data.

In this section, major emphasis will be placed on review and evaluation of the analytical methodology used in the CHESS program to assess population exposures to sulfur oxides and total suspended particulates. Conclusions will be general to all data taken at "official" CHESS monitoring sites, regardless of location. Where local differences in procedures or resultant data did occur, these will be described separately. Health studies, as described in the 1974 CHESS Monograph, that used aerometric data derived from non-CHESS monitoring sites will be reviewed separately.

1. SULFUR DIOXIDE

Atmospheric levels of SO_2 were determined using the EPA Reference Method, better known as the West-Gaeke or Pararosanaiine method. The specific details of this method are described in the procedures section of this chapter (Part B.1.). However, a few important aspects of this method will be reiterated. This reference method is basically a laboratory method adapted for field use. It is a "wet chemical" procedure relying on a gas-liquid phase chemical reaction between SO_2 and sodium tetrachloromercurate (TCM). To accomplish this reaction, the SO_2 as a gas phase pollutant, must be quantitatively absorbed into the liquid reactant solution. This is accomplished by bubbling ambient air through the solution at a controlled flow rate, thus, its description as a "bubbler method."

In an attempt to standardize the methodology and to eliminate problems associated with interlaboratory errors, a CHESS policy was instituted whereby all air sampling equipment was assembled and tested at the central EPA research laboratory and then shipped to the contractors for field use. Also, bubbler tubes were prefilled with the appropriate absorber solution, shipped to the contractor for their daily monitoring use, and shipped back to the central laboratory for chemical analysis. It was this long distance shipment of the chemical solutions that led to the first of a series of field-use problems with the procedure. These problem areas will be summarized below with an attempt to evaluate their net effect on the resultant CHESS SO_2 data. Following this summary of individual problem areas, an assessment of the overall SO_2 data quality will be given.

a. Spillage of Reagent During Shipment

The first field data were obtained in New York City and the Salt Lake area (Utah) in November, 1970. By mid-1971, field personnel at the Utah site reported to their CHESS field engineers that severe spillage was occurring during shipment. Many bubbler tubes were arriving partially filled with reagent and some were completely empty. At the Salt Lake area an attempt was made to refill with solution from extra tubes those tubes that were low. However, due to insufficient reagent, this was only partially successful. This problem was not officially recognized until October, 1972, at which time an internal EPA/CHESS memo was written outlining the problem and suggesting corrective action. The magnitude of the problem can be best assessed by quoting from the memo. "The present reagent tubes for SO_2 and NO_2 leak during shipment. . . . The SO_2 leakage rate (was found to be) 18% of the total volume, 50% of the time. . . . It follows therefore, that the resultant pollution data *are unreliable*." Recommendations were made in this memo as to possible corrective measures. These recommendations were not instituted until March, 1973.

During the subsequent years, many attempts were made to correct this leakage problem. However, none were wholly successful and as late as January 1975, another EPA memo described losses of solution in SO_2 bubblers during shipment and suggesting appropriate corrective action.

The effects of the reagent spillage problem on the SO_2 data can be only grossly estimated. Certainly, many samples were totally lost. These lost samples were not the major problem. Of more significance was the undetermined amount of daily SO_2 data that were in error due to the loss of sample by spillage and yet included in the network system.

If the reagent was partially lost during shipment to the sampling site and used as received, an increased concentration of TCM-SO_2 complex would occur relative to normal sampling. This potential positive bias would be corrected by for the analytical procedure used (Page A-6 CHESS monograph—Analysis Procedure). "At the laboratory, the sample is brought back to its original volume by the addition of distilled water to compensate for water loss during sampling." If however, the reagent spillage occurred after sampling, the required addition of water would result in data that were biased low in proportion to the amount spilled relative to the total volume of solution.

According to the EPA Memo of October, 1972, one half of all SO_2 data taken between November, 1970 and March, 1973 are likely to have been biased low by an average of 17%. This problem was corrected after April, 1973.

b. Time Delay of the Reagent—SO_2 Complex

The Reference Method as originally described in the Federal Register, was to be conducted at 20° C. There was a known error in the method associated with time delay between sampling and analysis which was dependent on temperatures. This error was derived from the spontaneous decomposition over time of the TCM–SO_2 complex as a function of temperature. The magnitude of the error and its exact dependence on temperature was not known but a brief study was conducted to determine its magnitude by scientists of the CHESS monitoring group in November, 1971. As a result of this study, a correction factor of +1.5% per day was arithmetically applied to all CHESS SO_2 data to compensate for the time delay between sampling and analysis.

A more recent and comprehensive study has been carried out within the Quality Control Branch, Environmental Monitoring Laboratory at EPA on the effect of temperature on "The Stability of SO_2 Samples Collected by the Federal Reference Method." This study indicated a much more severe problem than was estimated by the original CHESS study. The evaluation was carried out over the range of 35 to 278 $\mu g/m^3$ SO_2 concentration. The following findings were presented in the report:

> Over a normal range of temperature, the rate of decay of the TMC–SO_2 complex increases five-fold for every 10°C increase in temperature, respectively.
>
> The rate of decay is independent of SO_2 concentration.
>
> At 20, 30, 40, and 50° C the following SO_2 losses were observed: 0.9, 5, 25, and 74% loss per day, respectively.

This study makes abundantly clear a second and even more severe error associated with the SO_2 measurements conducted by CHESS. During the summer months, when the SO_2 absorber solutions were subjected to high and unknown temperatures between field sampling and laboratory analysis, significant degradation of the samples did occur. Estimates of time delay between sampling and analysis range from 7 to 14 days. Estimates of summer temperature exposures range from 25 to 40° C being most severe for the Utah CHESS sites. Thus, CHESS SO_2 data can be estimated to be negatively biased, mainly during the summer months. It would normally be difficult or impossible to estimate the magnitude of the bias except to say that it is probably large. However, simultaneous SO_2 measurements were taken by the New York City Department of Air Resources and by the Utah State Division of Health. These results were obtained by an independent method not susceptable to the temperature related error. A consistent pattern emerged when side by side data are compared. From May to October, the CHESS SO_2 data were low with the largest error occurring in the middle three summer months. The magnitude of the error varied from month to month and year to year, but the CHESS data were consistently low and represented only a portion of the true ambient SO_2 concentration.

c. Concentration Dependence of Sampling Method

The SO_2 reference method was subjected to a collaborative study program in 1973. Four participating laboratories tested the 24-hour version of the Federal Reference Method. A previously unknown source of error was documented that applies to the CHESS SO_2 data. It was found that the 24-hour sampling method does have a concentration dependent bias which becomes significant at the high concentration levels (200$\mu g/m^3$). Observed values tend to be lower than the expected (known) SO_2 concentration levels. This error source will yield a negative bias on the daily CHESS SO_2 data when they exceed 200 $\mu g/m^3$ and on all monthly and yearly average data.

d. Low flow correction

The determination of atmospheric SO_2 concentration was dependent on, among other factors, the accurate measurement of air that passed through the TCM solution. This flow was controlled by a critical flow orifice in the form of a standard hypodermic needle. In practice, the air flow through the sampling system was measured at the start and end of each 24-hour sampling period. This was done to detect low flow due to needle blockage. The Federal Register Method (Reference Method) calls for an air flow of 200±20 ml/min. In field operation, the CHESS procedure substantially broadened these tolerances. Replacement needles were installed if the initial air flow was greater than 220 ml/min which is consistent with the Reference Method; however, needles were not replaced nor were samples voided until the measured flow dropped below 100 ml/min. Integrated flows were calculated by assuming a linear decrease in flow between the start and end of the 24-hour sampling period. If, however, the needle was partially blocked near either the beginning or the end of the sampling period, the linear flow correction would be in error. Using the Reference Method flow tolerance, only small errors would be introduced by this correction (less than 10%). Using the CHESS procedure, however, errors as large as 50% could be introduced and not detected. These errors would be random (either positive or negative) depending on when during the sampling period the needle blockage occurred. Thus a large random error component was added to the SO_2 daily data but this component was somewhat damped statistically in the monthly or yearly averages.

The modification of flow tolerance by the CHESS aerometric group is a procedure that would not have withstood the critical review of a competent quality assurance program.

e. Bubbler train leakage

The West-Gaeke method, as described in the Federal Register, employs a vacuum bubbler train. That is, the sampled air is drawn through the bubbler train by a vacuum pump rather than being pushed through by a positive pressure pump. There are many advantages to the vacuum procedure, most important is that the air does not come in contact with any internal pump mechanism. However, there is a modest pressure differential between the atmosphere and the internal bubbler; thus all fittings and joints must be gas tight. The bubbler train used in the CHESS program had two points where frequent air leak problems were encountered. One was around the rubber stoppers for the bubbler tube and moisture trap and the other was the rubber tubing used to hold the glass assembly pieces together. Field operators reported consistent problems with leakage in the routine field use of the bubbler train. In a severe leak situation, the samples were voided due to out of tolerance (Low) flow rates. There were many cases however, where small leaks occurred but the final flow was within specifications so the sample was included as valid. In cases where the leaks formed around the rubber stoppers, no significant error would be introduced except due to the linear flow correction as applied to instantaneously developing leaks. This error is similar in nature to that discussed in the flow section. In the case of leaks upstream of the bubbler train, room air instead of outside air is drawn through reagent. In normal situations, it has been observed that room air is significantly less polluted than outside air. (See page 6–6, CHESS Monograph—comparison of school air to outside air). This effect may not be as large for the small buildings used to house CHESS stations, but a somewhat decreased pollutant level would undoubtedly be sampled. The absolute magnitude of this error cannot be adequately assessed but it can be stated that the error would be in a negative direction, that is, again to underestimate SO_2 levels.

2. GENERAL ASSESSMENT OF CHESS SO_2 DATA

The SO_2 data, accumulated at "official" CHESS sites, followed a remarkably uniform trend as the program progressed. The method used was the EPA Reference Method which is specific for the chemical species, SO_2. Thus, regional changes in pollutant mix, i.e., the proportion of other pollutant species relative to SO_2, had minimal effect on the SO_2 data. However, the sum effect of the errors detailed in this section did have a profound effect on both the accuracy and the precision of the data.

Under normal circumstances, a retrospective evaluation of a monitoring effort that occurred a number of years in the past and which had been terminated, could yield only the broadest of estimates of data quality. Fortunately for this review, two geographically different locations with six different monitoring sites were involved in the collection of simultaneous SO_2 data. Further, the groups responsible for the two data sets were managed independently and the methodology used was also independent. This fortunate circumstance enabled the reviewers to acquire a quantitative understanding of absolute differences among data sets as well as correlations with respect to time.

The locations where side by side data existed were the New York City sites at Bronx and Queens and the Salt Lake Basin sites at Ogden, Salt Lake City, Kearns, and Magna. In these locations, the local environmental monitoring agencies had sites located within 50 meters of the CHESS sites and at similar elevations. At these sites, the local agencies collected daily SO_2 and TSP data for the entire life of the CHESS program. The SO_2 methodologies used by both State agencies were variations of the peroxide bubbler method in which twenty-four 1-hour samples were integrated to form a single 24-hour SO_2 measurement. In New York the samples were measured acidimetricly and in Salt Lake City they were quantified conductiometrically. Neither method is as specific for SO_2 as is the Reference Method, that is, pollutants that are in a significant concentration, relative to SO_2 and that also oxidize to form an acidic compound will be interpreted as SO_2. For this reason, when the NYC Department of Air Resources initially brought to the attention of the CHESS Aerometric team the large discrepancy between their respective data, the discrepancy was dismissed as method bias on the part of the New York method. An EPA memo dated November 3, 1971 described a limited study into the Reference Method. The conclusion reached was "On the basis of (this study) . . . I feel there is no sound basis for discrediting the EES (Environmental Exposure System) methodology."

No further attempt was made to uncover the cause of the discrepancy in SO_2 data. Had the CHESS EES team obtained and compared the Salt Lake Basin data, especially that from Magna site, a disturbing similarity would have been immediately apparent. This data confirmed in detail the discrepancies observed in New York. It is important that the Magna site data were confirmatory since it was in a region of single source pollution, that from the nearby copper smelter. In this site very low levels of other pollutants existed relative to SO_2, thus the peroxide method was capable of giving reasonably reliable estimates of the SO_2 concentration. Of equal importance the general pollutant mix was very different between this rural smelter site and the urban area of New York City. Despite these differences the comparison of side by side Federal-State data indicate the same discrepancies in both trends and absolute concentrations. The following conclusions as to SO_2 data validity can thus be reasonably drawn from the review of methodological errors and the comparison of existing side by side data.

From November 1970 until December 1971 the SO_2 data generated from CHESS sites using the modified Reference method were biased low by 50 to 100 percent in the High Exposure sites when compared with existing State SO_2 data. Thus, the 1971 annual average SO_2 exposure estimates of $60\mu g/m^3$ as reported for Magna in the CHESS monograph (page 2–24) are more likely in the vicinity of $100\ \mu g/m^3$. Also, the same phenomenon occurred in New York and the reported values are also in similar error.

A confirming fact is that during cool months *after* 1971 SO_2 data correlated well both in trends and absolute concentrations between State and Federal analyses. It thus seems likely that the State data were reasonably accurate throughout that time period. However, one consideration must be applied here: namely, *that due to the difference between the independent methods an error bar of at least one hundred percent must be applied to the data and explicitly correct data cannot be drawn from these observations.* In other words, where two or more independent observations are in disagreement by a significant amount it cannot be said by inference alone that one data set is more correct than the other. It is reasonable to assume, however, from our review of all State and Federal data in the time period of 1970 through 1971, that the Federal SO_2 data as collected in the CHESS program were substantially low and went through an abrupt upward transition in concentration in December 1971 at all CHESS sites and Federal data taken before that time may reasonably be expected to have a large, unknown negative bias.

In November 1971, the CHESS monthly mean SO_2 data underwent an abrupt change in the positive direction. The cause of this change is not apparent. However, the result was profound. From that time until the conclusion of the CHESS program in July of 1975, the fall-winter data were in very good agreement with other existing data and very likely gave reliable estimates of SO_2 exposures.

Throughout the entire program, the CHESS SO_2 data had an associated negative bias during the summer months, becoming most severe during the hottest periods of July and August. This error usually reached a maximum of 60 to 80 percent underestimation of exposures and was variable. As a result, even though wintertime monthly SO_2 averages appear valid from 1972–1975, annual averages of the same data are biased low due to the inclusion of the summer errors. The best estimate of error in the annual average data 1972–1975 is approximately minus 15–20 percent relative.

The individual daily SO_2 levels, when compared to city or State data or to replicate CHESS measurements taken after 1973 had so large a random error component that they are not useful to assess daily SO_2 exposure (as attempted in the asthma panels). The random errors associated with the daily values were much larger than the differences observed over time.

Due to inherent methodological errors, the following may be considered as minimum differences between High and Low SO_2 exposures which may be considered "real." These are based on EPA's collaborative study of the reference method and used a 95 percent confidence interval.

Below 100 $\mu g/m^3$ SO_2, a difference of at least 50 $\mu g/m^3$ is necessary to be statistically significant.

Between 100 and 300 $\mu g/m^3$ SO_2, a difference of at least 60 $\mu g/m^3$ is necessary to be significant.

Below 25 $\mu g/m^3$, a single determination is not significantly different from zero.

3. TOTAL SUSPENDED PARTICULATE

The Reference Method for the determination of total suspended particulate matter (TSP) is probably the simplest and most reliable method used by CHESS. It has been well studied and most error sources are known. However, it is a method that measures an arbitrary and poorly defined portion of the total atmospheric particulate burden and the portion measured has unknown relevance to the human respirable portion. The size fraction measured is somewhat dependent on the design of the shelter used for Hi-Volume sampler. The design and dimensions of the Reference Method shelter are specified in the Federal Register, thus the portion of TSP that is collected by the method is generally uniform. Best estimates of particle size range included in the Reference Method are from 0.05 to 60 μm diameter. Above 60 μm diameter, the particle fall velocity is too great to navigate the bend around the roof of the shelter. Below 0.05 μm the collection efficiency of the glass fiber filter used in the method diminishes.

A collaborative study was conducted on the Reference Method using 12 different groups sampling ambient air at a common location. The results of this study indicate the method is capable of reproducible measurements with less than 5 percent error at the 95 percent confidence level. Also, the minimum detectable amount of TSP is approximately 2 $\mu g/m^3$ for a 24-hour sampling period. This sensitivity is more than sufficient for most 24-hour TSP measurements.

The TSP measurement method, as used in CHESS, had one notable difference from the laboratory procedure which was collaboratively studied. The weighing procedure to determine TSP was performed at EPA/RTP laboratory not by the CHESS contractors on site. This necessitated the shipment of individual filter samples through the mail and the subsequent storages of the samples at EPA. During laboratory reorganizations at RTP, periods as long as 6 months elapsed between actual field sampling and laboratory analysis.

The following is a summary of individual errors and an assessment of overall TSP data quality.

Loss of particulate matter before weighing

In the TSP methodology there were field-related procedures that resulted in partial loss of particulate matter from the Hi-Volume filter samples. Due to the exposed location of the Hi-Vol TSP samplers, wind and cold sometimes made it very difficult to remove the filter paper from the apparatus without losing part of the sample. No estimate has been made of loss due to this problem; it would, of course bias the reported results only in the direction of lower-than-actual atmospheric loadings. This was not a constant problem among CHESS sites. It was noted by field operators as being a particularly severe problem in the Salt Lake City area during the winter months.

Two other error sources have been identified in the determination of TSP, both of which would also produce a low-side bias: (1) the shaking-off of particles from the filter during transit from the field site to EPA/RTP, and (2) the evaporation of organic substances. In an attempt to quantify the mass loss during transit, David Hinton, EPA/RTP, made a comparison of filters collected in Utah, before and after mailing from Salt Lake City to RTP (22). He found that there was a average 4 percent loss. Carl Broadhead, of the Utah Division of Health, conducted a similar comparison; however, he noted an apparent loss of approximately 25%. This difference may, in part, be due to the time of year the studies were conducted, During the dry summer months in the Salt Lake City area, much of the TSP loading is due to windborn crustal material (sand). This material is much more easily lost in sample handling that is the finer anthropogenic particulate material.

A final error source, one more difficult to assess, derives from wind velocity versus collection efficiency. On days with relatively high wind (>15 mph), the Hi-Vol sampler is more susceptible to the inclusion of large diameter particulate material. To compound this problem, the design of the shelter makes the magnitude of the error dependent on the wind direction relative to the orientation of the shelter. The main result of this problem is that two side by side Hi-Vol samplers, oriented 90 degrees relative to each other, will produce dissimilar measurements with the discrepancy increasing as the daily wind velocity increases.

The overall effect of the summed errors with the Hi-Vol TSP measurement is a slight negative bias. This bias may be as small as 10% or may be as large as 30%. Side by side data from New York and Salt Lake indicate that this assessment is reasonable. These data also indicate that the TSP data were by far the best quality data taken in the CHESS monitoring program. Differences measured between High and Low sites are probably reasonable estimates of the differences of TSP exposures as received by populations within these areas. Some local source variations undoubtedly did occur, but average annual exposures were reasonable.

In any overall assessment of the CHESS TSP data it should be noted that all of the sources of errors mentioned previously related almost exclusively to the loss of large particulate matter and most likely that matter is associated with crustal weathering. This material is outside of the normal human respirable size fraction and by composition, it would be unlikely to be associated with aggravated health. Thus, loss of that portion of the total material may not have diminished the quality of data for health effects studies. It may in fact have rendered that data a closer estimate of the respirable TSP exposure to which the CHESS population groups were subjected.

It has been suggested by some environmental scientists that whenever Hi-Vol measurements are made for health related studies, the filter pads should be "shaken out" much like a housewife does when shaking crumbs from a used tablecloth. The resultant TSP exposure estimates derived from such a procedure would then more closely relate to the human respirable size fraction of the total atmospheric particulate burden. Although never actually implemented, this suggestion indicates the general level of dissatisfaction with the TSP Hi-Vol measurement method.

4. TOTAL SUSPENDED SULFATE

The determination of atmospheric sulfate concentrations, as carried out in the CHESS program, was a methodological extension of the Hi-Vol TSP method. Thus, all errors associated with the TSP method also affect the sulfate method. Subsamples were cut from the exposed Hi-Vol filters and were analyzed for total water soluble sulfate. Methods available for sulfate analysis at the time of CHESS determined all water-soluble sulfates as a class rather than distinguishing them by chemical species. Two different methods were available for total sulfate and both were used in CHESS. From November 1970 until September 1971, the manual turbidimetric method was employed. From September 1971 until July 1975, the methylthymol blue (MTB) method was used. The methods are somewhat similar and are described in detail above.

The turbidimetric method is subject to interferences, many of them being other common pollutants. In areas like the Salt Lake Basin where the pollutants are dominated by a single source, the procedure may be adequate. However, in urban areas like Cincinnati or New York City, where the pollutant mix is derived from many independent sources and is variable even within the city, the method is capable of only the crudest estimates of sulfate levels. It should not be thought of as an accurate measurement of atmospheric sulfate. Especially, small differences between High and Low exposure communities, such as were reported in the Cincinnati Study in the CHESS Monograph (page 6–5) cannot be identified as real differences. When a realistic error estimate is applied to the reported sulfate concentrations, the difference becomes statistically insignificant. Any correlation of CHESS health effects with sulfate levels where the sulfate data were obtained using the turbidimetric method must be carefully qualified.

The MTB method is basically a better measurement method because most of the aerometric interferences have been eliminated by its revised methodology. The two remaining interferents, phosphate and barium, are not normally found in atmospheric concentrations high enough to cause inordinate problems. However, problems associated with the sampling aspect of the method have been documented and do impact on the general CHESS sulfate data quality.

First, problems associated with sulfate blanks (the level of sulfate on the filter pad as manufactured) were reported to be high and variable. In the 1971–1973 time period, problems of variable blanks within the EPA NASN program were documented. The general blank level was equivalent to an atmospheric sulfate concentration of 1–2μg/m^3. However, the major problem was variability of the blank among manufactured lots of the filters. The blank level often varied by more than 100 percent among lots so that routine and continuous blank assessment should have been mandatory.

No evidence of routine sulfate blank determination was found in the CHESS monitoring program until 1974. From that time period on, adequate blank assessment and correction were applied to the data. From 1971 until 1974 however, the blank contribution to the CHESS sulfate data was not adequately assessed and consequently a positive and highly variable bias of unknown magnitude was included in the data.

Second, adsorption of atmospheric SO_2 onto the fiberglass filter material followed by spontaneous oxidation of the SO_2 to sulfate had been well documented. A 1966 publication by R. E. Lee and J. Wagman provided results of their investigation of the problem. The conversion was clearly documented with severe effects demonstrated on four-hour samples. The conversion did appear to be an active-site catalytic conversion that decreased in magnitude after an initial saturation of sites. Thus, 24-hour samples were much less affected by this problem than were those taken for shorter time intervals. Even so, the paper by Lee and Wagman, presented data in which routinely 0.5 to 1 μg/m^3 of the measured sulfate was derived from SO_2 conversion products. The maximum conversion presented was 2.1μg/m^3 derived from SO_2; this constituted a 10 percent positive bias of the sulfate data. A more realistic average bias is likely in the 5 percent range. However, there is clear evidence that in regions of high levels of SO_2, relative to sulfate, the positive measurement bias becomes much more severe. This is probably the case in the Salt Lake Basin area.

The third and most devastating problem associated with the CHESS sulfate data occurred when the laboratory analysis of sulfates was contracted to an outside firm. During this time period (October 1972–June 1974) the reported sulfate data underwent a sudden and sustained decrease in apparent atmospheric sulfate level. Upon investigation it was determined that the laboratory analysis of all sulfate data from all CHESS sites were biased low by approximately 50 percent. The reason for this negative bias was and still is not completely clear, but the continued dissemination of poor data was clearly due to inadequate quality controls. An interim EPA report on a retrospective quality assurance evaluation of CHESS Sulfate Data states:

> A quality control protocol was designed for CHESS chemical analysis but has not been implemented as per the contract . . . . The quality control protocol should be implemented immediately.

In a series of following studies the magnitude of the affected data and of the error were documented and an attempt was made to correct and therefore recover the data. This type of procedure is difficult at best and impossible in most cases. The validity of this data correction was again assessed by the EPA Quality Assurance Branch. Their finding was:

> The basic question . . . is—How does one make bad data good? Whatever is tried will be attacked for a multitude of (justifiable) reasons. Using the existing data set for relative pollution level assessment will be acceptable, but statements concerning absolute levels will not be. It would not be wise to submit these data to the NADB,[1] but rather answer all requests for these data internally.

Their statement gives a reasonable assessment of the CHESS sulfate data between 1972 and 1974. The assessment of other year CHESS sulfate data is more difficult. No comparative sulfate data exists from the local agencies as it did for SO_2 and TSP. Based on the intrinsic capabilities of the methods, and the error assessment of the field use procedures, it can generally be stated that:

1. From 1970 to September 1971 the sulfate data were obtained using the turbidimetric method. It should be used only as a sulfate level indicator. Due to interferences, there will be severe problems if an attempt is made to correlate sulfate levels in one part of the country with sulfate levels in another.
2. From October 1971 until October 1972, the data are subject to the following considerations:
    a. The data are likely biased in the positive direction from 1–2 $\mu g/m^3$. This bias may be more severe in areas of high SO_2 concentration relative to sulfate.
    b. The random error component of the measurement is probably in the order of ±25% at an atmospheric concentration of 10 $\mu g/m^3$.
3. From October 1972 until June 1974, all CHESS sulfate data were biased negatively by approximately 50% on an annual average basis due to improper laboratory analysis by the contractor. These data should be used only on an adjusted annual average basis to establish local trends within site locations. The unknown cause of the bias prohibits use of the data in shorter time structure (i.e., day, week, month) increments.
4. From July 1974 until July 1975, CHESS sulfate data underwent a marked improvement and was somewhat better than that collected in the 1971–1972 era. The positive bias of the data is probably similar to that of the earlier period but the random error component was improved due to improved sulfate blanks on the TSP filters.

D. The CHAMP Air Monitoring Program

1. INTRODUCTION

Early in the execution of the CHESS program in 1969, a number of staff members in the air quality measurements organization of EPA decided it was desirable, indeed imperative, to improve the efficiency and accuracy of short-term air quality data monitoring coverage. EPA coined the term CHAMP (Community Health Air Monitoring Program) for this concept of a second generation automatic system of air monitoring stations. Seven prototype stations were operated in California from January, 1972 to February 1974. The manpower ceiling placed on EPA resulted in a decision to contract for the development, installation, and operation of the CHAMP system. A contract for the development of the CHAMP system was awarded in February, 1973. The developmental monitoring system was to contain the newest technology in monitoring instrumentation. Accurate measurement of all critical air and liquid flows in the system was incorporated to enhance the accuracy of the system. The development continued to mid 1974 when the first station systems were installed in the Los Angeles area for field evaluation.

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[1] National Aerometric Data Bank.

2. SYSTEM DESCRIPTION

The CHAMP air quality measurement system assembles the available discrete pollutant measurement devices and associated meteorological instruments into a complete system in an air-conditioned portable building. EPA specified the pollutants to be measured and selected the instruments with the advice of the CHAMP contractor. All data are recorded digitally in a mini-computer integral to each system. The data are checked and stored on tape at each CHAMP site for transmittal to the EPA/RTP Laboratory at Durham, North Carolina. SO_2 and NO_2, and TSP measurements are also taken periodically using older CHESS-type bubblers and Hi-Vol sampler instruments described previously for backup and validation of the CHAMP instruments. These bubbler and filter samples are sent to the contractor's chemical laboratory in California for analysis.

All the CHAMP systems measure ozone, total gaseous sulphur NO/NO_2, TSP,/RSP combinations, temperature, wind direction and velocity, and humidity. Selected systems also incorporate CO and hydrocarbon sampling. The CHAMP system while automatic in principle, requires periodic calibration and servicing by an operator to maintain a high duty factor and an acceptable quality of data (less than 15% error band). The operator repairs and adjusts instruments as required, checks for failures, and does periodic calibrations and data verifications. A quality assurance specialist continually spot-monitors the CHAMP sites carrying-out calibration and quality checks.

It should be noted that the instrumentation of the CHAMP stations is not completely uniform. Some stations do not have wind and pressure instruments; not all have CO and hydrocarbon instruments.

The manner in which meteorological data from the CHAMP stations is being analyzed and used has not been investigated. This is a subject of interest depending on the future of the CHAMP program.

CHAMP stations were visited in Thousand Oaks, California, and Salt Lake City, Magna, and Kearns, Utah. The kind of meteorological instruments in use appeared to be appropriate and they appear to be well-located and properly maintained. Problems have occurred with new dew-point measuring equipment that is now being replaced (this has to do with humidity measurement. Except for occasional failures of the sensing element of the dew-point apparatus, collecting meteorological data from the CHAMP stations should be routine.

There are at present 18 CHAMP stations on line at locations selected by EPA; six in the Los Angeles Basin, three in Birmingham, Alabama, four in New York City, four in the Salt Lake Valley, and one at the EPA Health Effects Research Laboratory at Research Triangle Park, North Carolina.

3. FINDINGS REGARDING THE CHAMP PROGRAM

As in the CHESS program, all the instruments incorporated in the CHAMP station were developed by the manufacturer for laboratory use. In fact, some non-commercial instruments were selected by EPA to try to use the most advanced technology. The CHESS experience has demonstrated the need for validation in field use and the contractor appears to be attempting to do this.

There was apparently some attempt to standardize on one instrument manufacturer for ease of maintenance, etc. Bendix ozone and NO_x instruments were employed. Flame photometric measurement was selected for SO_2 EPA apparently was interested in a pulsed flourescence device but the equipment cost was too high for the budget. The present instrument actually measures total gaseous sulphur and it is assumed that this is SO_2. (The only other likely gaseous sulfur compound H_2S, does not seem to be widely present.) The rest of the measurements appear to be well-validated. The backup measurement with bubbler methods have validated NO_2, to the extent possible. The TSP/Hi-Vol measurements were apparently validated at the beginning of the CHAMP program. However, because of the non-linear calibration character of the flame photometric instrument in the low concentration ranges of interest from 0 to 50 $\mu g/M^3$, calibration and range setting by the operator still results in 5% to 15% range of uncertainty in the total sulphur readings. Further, while the West-Gaeke bubblers used to check CHAMP SO_2 are stored at 70° F at the sites, they are shipped to the contractor's facilities for analysis without temperature control and are subject to the unpredictable temperature dependent decay of solutions prior to analysis. Thus, the SO_2 validation in the CHAMP system may be in greater error than EPA expects.

The execution of the CHAMP program has yielded validation and quality control of field measurements better than CHESS. However, there are clearly numerous unresolved problems with the operation which have led to delays in validating the data bank and which require high level attention for resolution before reliable quantitative aerometric data can be obtained.

The data processing was 2,900 data-days behind at the time of this investigation and no date agreed on for total backlog elimination. Drift of zero setting and data span of instruments have invalidated part of the earlier analyses. The data are only about 60 percent machine validated. Field operator problems have arisen possibly due, in part, to a lack of standardized operating procedures. Successful operation of the CHAMP system requires well-trained instrument technicians, and people of this high level of skill have not been employed in the past. Because of such circumstances, the SO_2 data obtained through 1975 have been lost and apparently are not recoverable.

Some months ago EPA found that significant data were lost in transmitting over leased lines to the RTP laboratory. Thus, the primary data source is the data tapes from the CHAMP site computer which are mailed to RTP.

The CHAMP contract is up for renewal in November 1976 and the bids are being solicited competitively. It is believed that at this time competitive bidding could be a destabilizing step in this program and could delay the achievement of reliable routine data gathering another year. On the other hand there are obvious advantages to open competitive bidding. When system development is more nearly complete, it would certainly be appropriate for competitive bidding to be adopted. The competition should include quality control considerations. Unfortunately, the EPA quality assurance group was not consulted on the renewal request for proposal, although that group did participate in evaluating proposals received.

4. SUMMARY

CHAMP appears to be an improvement in real time field measurement of air pollutants in comparison with CHESS. However, the system is still not completely validated and may not be ready for routine use for 6 to 12 months. Data should not be stored in an accessible data bank until it is validated.

The present best estimate of expected accuracy is ±15 to 20% on the CHAMP measurements. However, this will be a significant improvement over previous CHESS aerometric network mesurement systems when and if it is realized.

V. REVIEW OF CHESS AIR QUALITY ANALYSIS PROCEDURES AND RESULTS

A. INTRODUCTION

This chapter presents the results of the investigative team's critical review of the utilization of aerometric data in the analysis and data modeling presented in the CHESS Monograph. The citations to pages, figures and paragraph numbers are to the 1974 CHESS Monograph. The findings are highlighted in terms of examples wherein it appears that estimates have been extended beyond the range of credibility, models have been misused, or miscellaneous errors of various types have occurred which lead to misinterpretation or overinterpretation of data or results of analyses.

B. USE OF ESTIMATED DATA

A serious weakness in the CHESS study was acknowledged in the last paragraph on page 7–9, which refers to the Salt Lake Basin study and the Rocky Mountain study. It is in part:

> Several factors should be remembered when interpreting the results of the lower respiratory disease studies . . . a majority of the pollution exposure data in both studies were estimated from emissions data.

This statement applies to one of the most important and controversial paragraphs in the CHESS report, also on page 7–9, which follows:

> It is interesting to note that larger increases in total lower respiratory disease and two of its components were observed in the High pollution community of the Salt Lake Basin study than in the corresponding communities in the Rocky Mountain study. Also, the mean annual suspended sulfate concentration was higher in the High pollution community in the Salt Lake Basin study than in the Rocky Mountain study; the opposite was true for sulfur dioxide. This suggests that increases in lower respiratory disease frequency are probably associated with suspended sulfates rather than sulfur dioxide.

The paragraph summarizes the argument that exposure to suspended sulfates over a period of years produces significant adverse health effects.

Analysis of the background material leading to the conclusion shows that it is derived from an interpretation of the relationship of four numbers all of which are estimated values. The sulfur dioxide values are estimated from smelter emissions and the sulfate values are estimated from estimates of sulfur dioxide in one case and estimates of suspended particulate based on smelter emissions in the other, assuming no difference in the ratio of sulfate to suspended particulate in the communities, Kellogg, Idaho; Helena-East Helena and Anaconda, Montana; and Magna, Utah.

The "High pollution community of the Salt Lake Basin" is Magna, Utah. It is less clear what is meant by the words "than in the Rocky

Mountain study". However, this paragraph refers to the preceding paragraph of the CHESS report, which speaks of concentrations, "as low as 7.2 $\mu g/m^3$ in the Rocky Mountain Study".

From this it can be concluded that reference is being made to concentrations of sulfates in Anaconda, Montana.

A comparison is being made, therefore, between average sulfur dioxide concentrations and average sulfate concentrations in Magna and Anaconda. The period of the records being compared covers the years 1968–1970.

From the preceding paragraph the values being compared may be obtained. They are as follows:

[The concentration values are given in micrograms per cubic meter, written as $\mu g/m^3$]

	Sulfur dioxide	Sulfates
Magna	92	15.0
Anaconda	177	7.2

Because of the methods used for making estimates, the absolute values of these concentrations are questionable. The next four sections discuss these estimates.

1. ESTIMATED SULFUR DIOXIDE CONCENTRATION, 92 $\mu G/M^3$ (MAGNA)

The concentration value 92 $\mu g/m^3$ for Magna can be obtained from Table 2.1.A.14 or Table 2.1.A.16. It is based on the following *estimated* values for three years:

Year:	$\mu g/m^3$
1970	84
1969	103
1968	90
Average	92

These estimates of annual sulfur dioxide exposures were derived by multiplying the yearly smelter emission for sulfur dioxide by the ratio of the 1971 measured annual average sulfur dioxide concentration (61.8 $\mu g/m^3$) to the same year's sulfur dioxide emission rate (193 tons/day). The last chapter established that these data could be off by 100 percent, probably on the low side.

$$61.8/193 = .320\ (\mu g/m^3)/(\text{tons/day})$$

The emission rates used were as follows (page 2–37):[1]

Year:	*Tons/day (SO_2)*
1970	261
1969	322
1968	281

In order to obtain the estimated sulfur dioxide concentrations, it must be first assumed that the meteorological conditions for each of the years 1968, 1969 and 1970, were identical to those conditions in

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[1] These rates of emission are off by a factor of two. Tons of sulfur, not tons of sulfur dioxide, are listed. These values corrected should be 522, 644 and 562 tons/day. However, this does not change the estimates of sulfur dioxide concentrations, which depend on a ratio between measured 1971 concentrations and 1971 emissions, whatever they might be. Doubling the emission rate also doubles concentations estimated by the application of a mathematical diffusion model (Page 2-23).

1971. There was no presentation in the Monograph of the use of climatological data to show that 1971 was similar to the other years, an average year, or a generally representative year. Even if the meteorological conditions for all four years had been identical, there is still a problem because the year 1971, on which the estimates are based is not a normal year for smelter operations. Emissions were zero, or practically zero for two weeks during July, and nearly zero for six weeks in July and August. Therefore, the emission/concentration ratio is deficient in showing the effects of the summer season, when wind direction frequencies from the smelter to Magna might have been less than during the remainder of the year. This suggests that the average concentration of sulfur dioxide in Magna is likely to have been slightly over-estimated, but it supports rather than changes the conclusion that average concentrations of sulfur dioxide are less in Magna than in Anaconda. Primarily this estimate is criticized because it is not supported by climatological information.

Also it should be realized that the method used for estimating the annual average concentration can result in an incorrect estimate if there is a significant background of sulfur dioxide from a source or sources other than the smelter. Multiplying the emission rate of the smelter by a factor assumes that all individual observational values that make up the annual average can be multiplied by this same factor, when actually only those values totally resulting from the smelter emissions would be effected. The Salt Lake City airport wind rose (Figure 2.1.2) is probably not representative for estimating the percentage of time that Magna is downwind from the smelter because the smelter stack is at the base of the Oquirrh mountain range. However, the frequency of west northwest and northwest winds at the airport suggest that Magna is only downwind about 5% of the time. Allowing for the effect of calm and variable winds, it seems unlikely that Magna would be under the influence of the smelter more than 10% of the time. It follows then, sulfur dioxide values for only these hours would be affected. On the other hand, if the smelter is the only significant source of sulfur dioxide, as may be the case, then multiplying individual observation values of zero concentration would yield only zero, and the procedure for estimating yields a true result, assuming no change in meteorological or emission conditions. Since the sulfur dioxide background in Magna is not known, the error that could be produced by background concentrations cannot be determined. Probably most of the sulfur dioxide does come from the smelter, so this source of error is not significant.

2. ESTIMATED SULFUR DIOXIDE CONCENTRATION, 177 $\mu g/m^3$ (ANACONDA)

A paragraph in the right hand column of page 3–12 explains how the average concentration of 177 $\mu g/m^3$ for sulfur dioxide was estimated for Anaconda for the period 1968–70 using sulfation plate data and emission rates. However, the explanation is incomplete, because it requires the 1971 emission rate of the smelter, which has been omitted from the Monograph. Thus, the validity of the entire procedure is impossible to verify. Table 3.1.2., which lists the emission rates by year begins with the year 1970. The ratio of $0.343 \pm .253$ $(\mu g/m^3)/(ton/day)$ was obtained by a very dubious procedure. To begin with, sulfation plate data are of somewhat uncertain nature. The document "Air

Quality Criteria for Sulfur Oxides", U.S. Department of Health, Education and Welfare, Public Health Service, National Air Pollution Control Administration, Washington, D.C., January, 1969, pp 24–25 says that sulfation "candles" (and plates) give only "an empirical estimate of the average concentration". It also says "results are influenced by wind movement and humidity" and that "the lead peroxide candle provides intelligence on the oxidizable sulfur compounds in the atmosphere which seldom can be directly related to sulfur dioxide".

The CHESS Monograph paragraphs refer to sulfation plate data for 1965. The sulfation plate is a variation of the lead peroxide candle. Developmental work on the plate was reported in the following reference: Huey, N.A. "The Lead Peroxide Estimation of Sulfur Dioxide Pollution" J. Air Pollution Control Association, Vol. 18, pp 610–611, Sept. 1968. Consequently it is unlikely that sulfation plates were in use in Anaconda in 1965.*

In order to determine sulfur dioxide from a lead peroxide candle or plate an empirical relationship must be used. For example, in the Helena Valley, Montana, Area Environmental Study, (EPA, Office of Air Programs, Research Triangle Park, North Carolina, January 1972) the sulfation values were converted to sulfur dioxide values by means of the relationship: 1 mg SO_3 per 100 cm^2 per day is equivalent to 0.035 ppm SO_2. In the history of the use of lead peroxide devices, there has not been general agreement as to what ratio should be used, and a belief prevails that sulfation candle or plate data are conservative, i.e., that sulfur dioxide concentrations are sometimes higher than indicated. Further, more information is needed concerning the location of the station, or stations, in the Anaconda area, where the sulfation data were obtained. In order to validate the Anaconda sulfur dioxide data further work needs to be done.

In 1965 the annual average concentration of sulfur dioxide was reported to be 80 $\mu g/m^3$ with an emission rate of 609 tons/day. Since the 1971 emission rate is omitted from the report it cannot be compared with the corresponding concentration of 286 $\mu g/m^3$. Assuming that the 1971 emission rate is also on the order of 600–700 tons/day, then there seems to be too great a difference between the 80 $\mu g/m^3$ concentration and the 286 $\mu g/m^3$ concentration. (Center paragraph, right hand side, page 3–12.)‡

The ratio 0.343 ± .253 has a large error factor. The range is from .090 to .597. If the low value is multiplied by the emissions for the years 1968–1970, the following concentrations are obtained:

[Tons per day]

Year	Table 3.1.2 (SO_2)	New value Montana SDES
1971	Omitted	636
1970	635	856
1969	545	824
1968	367	662
1967	346	459

NOTE.—The omission of the 1971 emission rates makes it impossible to check the effect of using the new value for 1971 on the estimated emission rates.

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*The chemical reaction for "candles" and "plates" is the same.

‡According to information recently received from the Montana State Department of Health and Environmental Sciences, the emission rates listed for the Anaconda smelter are low.

Year	SO_2 emissions (tons per day)	Estimated average concentrations ($\mu g/m^3$)
1970	635	57
1969	545	49
1968	367	33

The average of these values is 46 $\mu g/m^3$. This concentration is considerably less than the 92$\mu g/m^3$ value at Magna. However, information received from a representative of the Montana State Department of Health and Environmental Services, suggests that the 80 $\mu g/m^3$ value and the 286 $\mu g/m^3$ value were measured in two different locations in Anaconda, and that the 80 $\mu g/m^3$ value is too low. This indicates that the estimated values of sulfur dioxide in the table comparing Anaconda and Magna values are somewhat too low.

The estimates are further weakened by the fact that an assumption is made that meteorological conditions during all of the year is identical for all years. No supporting climatological information is presented.

Also, note that the Table 3.1.7 lists a sulfur dioxide concentration of 177 $\mu g/m^3$ for 1971 instead of the 286 $\mu g/m^3$ value obtained from the Montana State Department of Health.

The procedure for estimating sulfur dioxide concentrations in Anaconda seems unnecessarily crude, making the average concentration value for the years 1968–1970 uncertain. However, since the reported 1971 values for Anaconda and Magna are 286 $\mu g/m^3$ and 61.8 $\mu g/m^3$, and these values are the basis for estimates, it would appear that it was fairly certain that there was more sulfur dioxide present in Anaconda, than at Magna during the '68 to '70 period of the CHESS studies.

3. ESTIMATED SUSPENDED SULFATE CONCENTRATION, 15 $\mu g/m^3$ (MAGNA)

The 15 $\mu g/m^3$ estimate is a *double estimate* since the sulfur dioxide concentration data on which it is based is also *estimated*. The sulfate value seems to be an average for the years 1968–1970. It is obtained by using the following regression equation, which is found on page 2–39.

$$\text{Magna}-\text{SS}=0.09(SO_2)+6.66$$

This equation is based on 1971 conditions.

It is of interest to note that with a zero concentration of sulfur dioxide there would still be 6.66 $\mu g/m^3$ of sulfate, or approximately half the average annual value reported on 1971, which was 12.4 $\mu g/m^3$ Further, 44% of the 15 $\mu g/m^3$ of interest for the years 1968–1970 is unrelated to sulfur dioxide concentrations. The Figures 2.4.2 and 2.4.4 suggest some lack of complete correlation between sulfur dioxide and sulfate concentrations.

During the strike with zero sulfur dioxide concentrations, there still is an appreciable amount of suspended sulfate. Also, a peak value of sulfate occurred during the third week that does not correspond with sulfur dioxide value behavior during the same period. Similarly, the very large rise in sulfur dioxide that peaked in the ninth week hardly shows in the sulfate values. Consequently, the regression equation can be questioned because the reason for the sulfate values is not understood. What is the physical source of the sulfates?

Since the sulfur dioxide concentrations used in the regression equation are themselves estimated, uncertainties in the sulfur dioxide estimates are compounded in the sulfate estimates. Further, since the source of a considerable amount of the sulfate seems to be not associated with the sulfur dioxide, it is not clear what effect the strike period has on the estimates.

The CHESS report lists the suspended sulfate concentration as 12.4 $\mu g/m^3$ in 1971 and this is the basis for the estimate of 15 $\mu g/m^3$ for the 1968–1970 period. Observations of sulfate in Magna area subsequent to 1971 support the argument that average annual concentrations are in the neighborhood of 15 $\mu g/m^3$, or that they are significantly higher than reported for Anaconda.

On page 2–79, in Table 2.4.1, it may be noted that suspended sulfate values for the High community do not follow the sulfur dioxide concentrations, particularly for the Spring and Summer. This raises a question about using sulfur dioxide as an indicator of sulfate, as was done with the regression equation on page 2–39. (Median values for the High community are: Sulfur dioxide, Spring 64, Summer 9, whereas for suspended sulfate they are 8 and 7, respectively.)

Wind blowing from the smelter stack to Magna would generally cross a portion of the Great Salt Lake and, therefore, might carry more moisture, thereby facilitating the conversion of sulfur dioxide to sulfate. Perhaps this mechanism helps to account for the high sulfate concentrations observed in Magna.

4. ESTIMATED SUSPENDED SULFATE CONCENTRATION, 7.2 $\mu g/m^3$ (ANACONDA)

The 7.2 $\mu g/m^3$ suspended sulfate value can be obtained from Table 3.1.7, page 3–12, by taking an average of sulfate values for three years, as follows:

Year:	$\mu g/m^3$
1970	8.9
1969	7.6
1968	5.1
Average	7.2

These sulfate values are estimates, based on estimates of total suspended particulate and an estimate of the ratio of suspended sulfate concentration to total suspended particulate concentration, based on results from East Helena and Helena, Montana, and Magna, Utah. The same procedure was used for Kellogg, Idaho.

On page 3–11, in an attempt to explain how the suspended sulfate estimates were made for Kellogg, it is stated that "Data observed for Magna during the period January 1971–June 1972 indicated an average ratio of suspended sulfate concentration to total suspended particulate of 0.159." Following this is the reference number "22," referring to National Air Pollution Control Administration Publication No. AP-61, "Characteristics of Particulate Patterns 1957–1966." This publication presents graphs of suspended particulate concentrations for various cities over a ten year period. In it, suspended sulfates are not mentioned, the time period is wrong, and there are no data for Magna; therefore, it must be concluded that the reference is an error.

An obvious reference for this paper would have been the paper by Marvin B. Hertz, et al., "Human Exposure to Air Pollution in Salt Lake Communities, 1940–1971," however, it is not referenced. Perhaps this was the reference intended. Even so, the ratio 0.159 cannot be obtained from the Hertz paper.

In the Hertz paper, page 2–11, Table 2.1.2, which gives CHESS 1971 Annual Averages for Magna, the suspended sulfate concentration is 9.6 $\mu g/m^3$ and the total suspended particulate concentration is 53.9, which gives a ratio of 0.178. In Tables 2.1.5 and 2.1.A.16, the following concentrations are given: TSP, 66 $\mu g/m^3$, SS, 12.4 $\mu g/m^3$. Here the ratio is 0.188. Other ratios can be determined for various time periods from Tables 2.1.A.4 and 2.1.A.5, but none of these is 0.159.

Note (page 3–11) that the unexplained ratio 0.159 for Magna is used with the 0.063 ratio for East Helena to obtain the ratio 0.111 plus or minus 0.057 that is used to estimate suspended sulfate concentrations for Kellogg, and the 0.11 plus or minus 0.06 ratio for Anaconda (page 3–13).

(Pages 3–8 and 3–9) Particulate emissions for East Helena are given in two tables on pages that face each other. The headings of the second column in Table 3.1.4 should be "Emissions, Tons/year," not "Emissions, Tons/day."

On page 3–7 it is stated that estimates of stack emissions for both particulate and sulfur dioxide for East Helena for the years 1941–1970 were provided by Asarco. Presumably the data in Table 3.1.3 are Asarco data. The source of the data in Table 3.1.4 is not stated.

The Office of Air Programs Publication No. AP-91, Helena Valley, Montana, Area Environmental Pollution Study, gives more information about the industrial complex at East Helena. This study was conducted during the period June 1969 through June 1970. The table below is from this study.

EMISSIONS FROM EAST HELENA INDUSTRIAL COMPLEX

[Tons per day]

Company and operation	Emissions					
	SO_2 production			Particulates production		
	Reduced	Normal	Maximum	Reduced	Normal	Maximum
Asarco:						
Sintering	184.6	315.6	355.1	0.8	0.5	0.5+
Smelting	8.4	14.6	23.2	(1)	(1)	(1)
Miscellaneous	(1)	(1)	(1)	(2)	(2)	(2)
Subtotal	193.0	330.2	378.3	.3	.5	.5+
Anaconda:						
Fuming	13.0	13.0	13.0	(3)	(3)	(3)
Miscellaneous	(4)	(4)	(4)	1.0	1.0	1.0
Subtotal	13.0	13.0	13.0	1.0	1.0	1.0
American Chemet: Pigment production	(1)	(1)	(1)	(5)	(5)	(5)
Total	206.0	343.2	391.3	1.3	1.5	1.5+

[1] Negligible.
[2] The outside storage of concentrates contributes a significant but undetermined amount of particulates.
[3] Emissions also occur during the slag charging and the coal mill, but no estimates have been made.
[4] Emissions occur when slag is dumped, but no estimate of their quantity has been made.
[5] Emissions are controlled by cyclones and bag filters with high collection efficiencies.

It may be noted that ASARCO is only one of several particulate sources for the East Helena area. Fuming and other slag processing activities of the Anaconda Co. are estimated to produce 1.0 tons per day of particulates, resulting in a normal total of 1.5 tons per day, not a rate in the neighborhood of 0.3 tons per day as Table 3.1.3 suggests. Further, the total normal sulfur dioxide emission rate in the preceding table is 343.2 tons per day, a considerably higher rate than is given in Table 3.1.2. (i.e., 1969: 221 tons/day; 1970: 239 tons/day).

On page 3–7, right hand side, is given an explanation of how the data in Table 3.1.4 were used to obtain a ratio of total suspended particulate concentration to tons of particulate emitted per day for East Helena. However, after giving this explanation, the estimates of TSP in Table 3.1.5, that were used to make the suspended sulfate estimates were *not* obtained by means of this ratio. They seem to have been obtained from the particulate emission data in Table 3.1.3, using the factor 383.22 ($\mu g/m^3$)/(tons/day). The derivation of this factor is not explained. The ratio that is explained never seems to have been used. The suspended sulfate estimates are obtained by multiplying the total suspended particulate concentrations by the factor 0.063, which is explained on page 3–8.

Both observed and estimated suspended particulate concentrations are given in Table 3.1.4 and 3.1.5. It may be noted that the estimated TSP values are used to estimate the suspended sulfate concentrations and not the observed values for the years 1966 through 1969. In 1966, the observed value was 87 $\mu g/m^3$, whereas the estimated value is 114.2 $\mu g/m^3$. No explanation is given for rejecting the observed values.

Data for Magna during the period January 1971-June 1972 indicated an average ratio of suspended sulfate concentration to total suspended particulate of 0.159. The available data for East Helena indicated a suspended sulfate to total suspended particulate ratio of 0.063 ± 0.022 $\mu g/m^3$. For Kellogg, the assumption has been made that the ratio of suspended sulfate to total suspended particulate is the average of these values, or 0.111 ± 0.057. For Anaconda, this value was rounded to 0.11 ± 0.06. It is multiplied by the estimated concentrations of total suspended particulate listed in Table 3.1.7, to obtain the suspended sulfate values for each year.

The following table has been prepared from the Helena Valley study, June through October 1969.

Station	Location[1]		Suspended particulate	Particulate sulfate	Ratio
	Degrees	Miles			
1	34	0.8	108	3.5	0.032
2	105	2.5	74	3.7	.05
3	112	.4	59	4.4	.069
4	274	4.5	62	2.9	.047
Average			76	3.6	.050

[1] With respect to the smelter stack.

The data from stations 1 and 3, the stations nearest the stack, were used to obtain a ratio range (0.037, pages 3–8), but for some curious reason the available ratios from the Helena Valley study were not used. The average ratio for stations 1 and 3 is 0.051.

The ratio chosen for East Helena, 0.063 plus or minus 0.022 ($\mu g/m^3$)/($\mu g/m^3$), is not significantly different from that which might have been obtained had more use been made of the Helena Valley study, but there is no basis for the assumption that the ratio of suspended sulfate to suspended particulate is similar in Magna, East Helena, Helena, and Anaconda.

The dubious nature of using suspended particulate concentrations to estimate suspended sulfate can be seen by comparing Figures 2.4.3 and 2.4.4. In the Low Exposure Community, the sulfate level remains low and nearly constant while the suspended particulate concentrations fluctuate.

In the High Exposure Community, the highest concentration of suspended particulate occurred on the fourth week whereas the peak sulfate value occurred on the third week. On the fourth week, sulfate levels dropped. A corresponding drop in the sulfate levels does not occur until the fifth week. Only during the last seven or eight weeks do suspended particulate and suspended sulfate concentrations fluctuate together. There may be some situations where suspended particulate and suspended sulfate concentrations are well correlated. Justification for assuming correlation in the Salt Lake Basin and the Rocky Mountain communities is inadequately supported by scientific evidence presented in the CHESS Monograph.

Further, the 7.2 $\mu g/m^3$ suspended sulfate estimate for Anaconda is based on an estimate that comes from another estimate of suspended particulate values based on rates of emission from the smelter. During the period 1961–1962, the annual total suspended particulate concentration was found to be 84.5 $\mu g/m^3$. In 1971, the average suspended particulate level was observed to be 52 $\mu g/m^3$. By comparing the observed total suspended particulate concentration with the particulate emitted from the Anaconda plant, a ratio of 9.1 ± 2.3 ($\mu g/m^3$)/(ton/day) was determined. This ratio was multiplied by the particulate emission for Anaconda shown in Table 3.1.3 to estimate the total suspended particulate concentrations for the years 1940–1970. This ratio cannot be actually obtained from the data presented in the report because particulate emissions for the year 1971 are not given, i.e., they are not listed in Table 3.1.3.

The basis for this ratio is unfounded since there are sources for the suspended particulate other than the smelter emissions.

Although there are no actual sulfate observations from the Anaconda area included in the CHESS report there are some actual observations of suspended sulfate versus total suspended particulate available for the year 1971, that were obtained from the Montana State Department of Health and Environmental Sciences. These suggest that annual average suspended sulfate levels in Anaconda are in the neighborhood of 4 or 5 $\mu g/m^3$, even less than the estimated value (7.2 $\mu g/m^3$).

There are also pronounced seasonal effects, with much higher values in winter than in summer. The months of February and April had values of 7 and 9 $\mu g/m^3$ whereas the months of July and August have values of less than 1 ug/m^3. Local heating emissions and relative humidity may be significant factors determining the measured concentration as well as the smelter emissions.

5. ESTIMATES OF SUSPENDED PARTICULATE, SALT LAKE BASIN STUDY

On page 2-23 it is stated that "the number of sulfric acid plants utilizing sulfur recovered from emissions have increased from one in 1940 to seven in 1971, and that air pollution control devices in the form of baghouses, scrubbers, cyclones, and mist eliminators have been installed. Such changes in the smelter operations would greatly effect the ratio of suspended particulate to tons of copper produced. Therefore, aside from the fact that there would be differences from year to year because of meteorology, the procedure described in the first paragraph, right hand column, page 2-24, for estimating suspended particulate from copper production in tons for 1971, is highly questionable.

6. ESTIMATES IN THE CHIGACO AND NEW YORK STUDIES

In the Chicago and New York studies suspended sulfate concentrations were estimated from suspended particulate concentrations. In Chicago, the estimates were used to fill in data for some years when no data were available. In the New York study measured values for suspended sulfates for 1956–1970 were available from the Manhattan 121st Street station, and these values were used as citywide values. The observed annual ratios of suspended sulfate to dustfall for New York City were used to estimate the suspended sulfate levels in Queens and Bronx. In Table 5.3.1 suspended sulfate levels for the Low Community (Riverhead) are listed as about 10 $\mu g/m^3$ for the years 1961 through 1970. The basis for this estimate is not given, although it was probably determined from the 1971 concentration, which was 10.2 $\mu g/m^3$.

In summary, it appears that some values, on which are based important conclusions that sulfates may be harmful to health, are estimated values.

C. Use of Mathematical Dispersion Models

The dispersion model shown in Figure 2.1.16 is incorrectly applied. It was used in the Salt Lake Basin study to determine sulfur dioxide contours around the smelter source and to show that annual exposure estimates obtained from the ratio of 1971 observed air quality to 1971 emissions were not unreasonably high or low. First, the contours are incorrect because the model used does not take into account the elevation of the terrain and the wind direction frequencies for the Salt Lake City airport, which were used are different from those affecting the smelter plume, which originates at the base of the Oquirrh Mountains. Second, a dispersion model is based on numerous assumptions and applied in this way might be off by a factor of two, or more. It does not make sense to use a model to check observations.

The usual application is to apply observational data to calibrate, or verify, a model. A model such as the one used might have been applied to show some sort of relative distribution of concentrations across the Salt Lake Valley, however, it should not have been used to justify estimates of concentrations over the period 1940–1970. (See Tables 2.1.A.14 and 2.1.A.16). Further, during this review of the CHESS report it was discovered that smelter emissions used for the model estimates were tons of sulfur, not tons of sulfur dioxide. Therefore, the model estimate is only half what it should have been. Doubling the emission rate and reducing the wind direction frequency somewhat with respect to Magna might result in an estimated concentration near that measured, which was 61 $\mu g/m^3$.

Apparently the dispersion model was run only once and then the ratio between the emission at the smelter for 1971 and the calculated concentration was applied to emission values for the other years in order to obtain the other listed concentrations in the column headed "Diffusion Model". No account is taken of the fact that meteorological conditions, or perhaps stack conditions, were not the same for all years. More information should have been included in this report on exactly what meteorological data were used in the model. The model requires the use of the STAR program, which is obtained from the National Climate Center. Frequently the results of running this program are based on data for the year 1964, which is the only year when wind directions were punched on data cards to the nearest 10 degrees each hour rather than each 3-hours. Therefore, the model is likely to have incorporated meteorological data for some year other than 1971, the year of the emission data. No attempts is made to show that the year (or period) of the meteorological data is average, good or bad. Similarly there is no attempt to show that 1971 was an average year, yet all of the estimates are based on this assumption.

Considering how the model estimates for the years 1940–1970 were obtained it is misleading to include them in the table, and they serve little purpose since the ratio for the year 1970 is repeated throughout.

On page 2–43, bottom of right hand column, the following statements appear: "Estimates of sulfur dioxide, total suspended particulates, and suspended sulfate concentrations in the High exposure community for 1940–1970 and the Intermediate II exposure community for 1950–1970 were obtained by a mathematical dispersion model, which utilized emissions from the industrial source and extensive local meteorological data, and by observed relationships among pollutants. Observed suspended particulate, suspended sulfate, and sulfur dioxide concentrations for 1970–1971 were used to calibrate the models used to estimate exposure levels for previous years." This is an overstatement. The estimates were obtained from simple ratios and the application of a regression equation. See page 2–39. The model was only applied once to demonstrate that annual exposure estimates obtained from a ratio were not unreasonably high or low.

In the Chicago study, another attempt was made to apply a dispersion model (Figure 4.1.10). This model gives a false picture of pollution conditions that prevailed in the study area because it is based only on pollution sources within the city limits of Chicago, omitting effects of adjoining large industrial sources in Indiana and of some suburban communities to the southwest of the Loop area, which have considerable air pollution.

Maps recently published by the Chicago Department of Environment Control, for the years 1970 and 1975 clearly show that pollution concentrations are not simply concentric around the urban core as the model indicates.

On page 4–8, it is stated Measured data from the City network, from which the exposure estimates were made, were best supported by the Mitre model. It is not clear why a greater use was not made of the available actual measurements instead of the model estimates. Also, it is not sufficiently clear why the model happens to be for the year 1968.

VI. AN ANALYSIS OF THE CHESS HEALTH EFFECTS STUDIES

A. General Problems of Epidemiologic Investigations of Pollution Effects

Before discussing health effects problems specific to CHESS, some discussion of general difficulties inherent to pollution epidemiology may be helpful.

Exposure to suspect pollutants is not controlled in population studies. Indeed with current technologies, it is not possible to be sure that the correct pollutant is even being measured. Combinations of pollutants may be more harmful than any single pollutant, and the number of studies needed to investigate such synergisms (interactions) increases rapidly with the number of pollutants under consideration. The analysis of synergisms is often impractical since sites with the needed configurations of pollutants are seldom at hand.

Not only is exposure uncontrolled, it is often difficult to measure. Even when aerometric measurements are valid, special meteorologic conditions or personal habits may cause a given subject to experience pollution levels very different from those measured at a nearby fixed monitoring station. These problems are exacerbated in long term studies during which the quality of aerometric data has been variable and individuals have changed jobs and residences. Aerometric methods for measuring hourly or daily pollution levels are often less reliable than required for studies associating pollution levels with short term health effects.

The health measurements are often subjective responses to a questionnaire or interview. An individual may give one answer on a self-administered questionnaire and another to a friendly interviewer. Other factors, such as the public announcement of a pollution alert, can also influence subjective health measurements. Some health measurements, such as pulmonary function tests or blood analyses, are less influenced by poorly defined conditions surrounding the meaurements and are said to be objective. However, even objective end-points respond to uncontrolled events like an undetected influenza epidemic or high pollen count.

Whether the health measurement is subjective or objective, the response is often affected by factors (covariates) associated with the subject studied and unrelated to pollutant exposure. Whether the individual smokes or is subjected to cigarette smoke at home or work is a covariate of dominant importance in pollution studies. Educational attainment may affect responses to questions about phlegm or pneumonia. Occupation, age, sex, race, immunity to influenza, allergy, access to air-conditioning and countless other covariates complicate the interpretation of epidemiologic data. Epidemiologists treat covariates in two ways. They try to choose study populations which have similar covariate characteristics so that health differences between such populations can be ascribed to pollution effects. Alternatively, they make mathematical adjustments to nullify the effects of covariate imbalances. Both strategies have weaknesses, and neither works if the investigator is unaware of an important covariate or has failed to measure it.

The epidemiologist has little control over the subjects studied. He cannot assign them at random to reside in polluted communities of interest. Thus, a clean town may contain many asthmatics because asthmatics have wisely chosen to live there rather than in a more polluted community. This fundamental problem of self-selection must qualify any conclusions obtained from non-randomized population studies: it may be possible to demonstrate temporal or spatial associations between health and pollution measurements, but a causal relationship cannot be inferred on the basis of a single epidemiologic study.

Students of pollution counter these weaknesses in several ways. One strategy is to replicate an epidemiologic study in a variety of circumstances and serially in time. If a consistent association between pollution and health measurement is observed, it is held to be reliable since covariate imbalances and problems of self-selection are unlikely to affect all sites and to persist over time. Clinical studies, in which healthy volunteers are subjected to controlled pollution exposures, and toxicological studies, in which animals are subjected to various combinations and doses of pollutants, complement information obtained from epidemiologic studies. This body of information from clinical and toxicological studies and from several epidemiologic studies may substantiate an interesting association suggested by the health and pollution measurements of a single epidemiologic study.

In addition to these general issues, several questions directly pertinent to the CHESS health measurements were examined, namely:

(1) Was the health measurement a reliable and meaningful indicator of public health?

(2) Was the statistical analysis sound and impartial?

(3) Were the methods used to ascribe specific health effects to specific pollutants and to establish dose-response relationships logically compelling?

The sources of information used in this assessment include:

(1) The CHESS Monograph cited previously which contains data gathered in 1970–1971 as well as some earlier studies.

(2) Preliminary internal EPA drafts of 1971–1972 studies.

(3) External peer review documents.

(4) Interviews and progress reports of contractors and EPA personnel who gathered health and aerometric data.

(5) Interviews with EPA personnel who gathered and analyzed the data.

Time limitations prohibited a complete reanalysis of the primary health and aerometric data.

B. INTRODUCTION AND DEFINITIONS

What follows is a detailed discussion of each type of study found in the CHESS Monograph. Each health measurement is considered together with special problems associated with particular CHESS sites. Comparisons across CHESS sites and comparisons with subsequent CHESS studies are made (when possible). A relatively nontechnical summary follows the discussion of each health measurement. Unfortunately, much of the terminology is specialized. A short glossary of statistical terms is given below for those who wish to read the detailed assessments. This glossary is intended to convey the purpose and use of certain statistical terms rather than to give precise definitions, which are available from standard statistics texts. The definitions are particularized to pollution applications.

Adjustment Procedure.—This is a mathematical method, based on an assumed model, to compare populations exposed to various pollution levels when other factors which might affect health measurements, such as age, sex, or race also differ among communities.

Autocorrelation.—This term describes the way in which the asthma attack rate on a particular day depends on the attack rate on other days. Pollution levels, which are also time series, also have autocorrelation structure, since a pollutant which is elevated above usual levels on one day is likely to be elevated on the next day also.

Correlation.—Correlation is a measure of the strength of the linear relationship between two quantities. Positively correlated quantities tend to rise and fall together, whereas negatively correlated quantities tend to rise and fall out of phase.

Goodness-of-Fit Statistic.—This quantity is used to gauge how well a mathematical model fits a set of data.

Least Squares Method.—This is a method of estimating the parameters of a mathematical model so that the final estimates bring the model into closest possible congruence with the data.

Linear Model for Categorical Data.—Linear models are models in which the average value of the observation (dependent variable) is assumed to be a linear function of independent variables, such as pollution category, age or sex. If the expected frequency of a cell in a contingency table is assumed to be a linear function of such independent variables, one has a linear model for categorical data. The value of such a model, if it fits the data, is that it enables one to estimate the relative contributions of the various independent variables.

Multiple Regression Analysis.—Multiple regression analysis is a method for relating an observation (dependent variable) such as asthma attack rate to several independent variables, such as suspended sulfate levels, sulfur dioxide and perhaps other pollutants. Usual applications require that the expected value of the observation is a linear function of the independent variables, and that observations are statistically independent with constant variability about the expected value. A multiple regression model can be used to describe a given set of data and to predict the outcome of future observations for known values of the independent variables. However, the fact that a multiple regression model fits a given data set well or yields good predictions of future observations need not imply that the independent variables determine the observations or bear any causal relationship to the observations.

Pooled.—Pooled data is data obtained by combining data from two or more samples and then ignoring the fact that the combined data came from various sources.

Residuals.—Residuals are differences between observed data and values expected under a mathematical model. Residuals are helpful in assessing the appropriateness of the model.

Ridge Regression.—If independent variables are highly correlated, estimates of the effect of a particular independent variable on the dependent variable can be greatly influenced by what other independent variables are included in the multiple regression model. Ridge regression is a method of determining the importance of a particular independent variable in the presence of other highly correlated independent variables.

Statistical Significance.—A statistical hypothesis is tested by computing how probable a set of data is under that hypothesis. This level of probability is called the significance level and a level $p < .05$ means that the chances are less than 5 in 100 that the observed outcome could have occurred if the hypothesis were true. The significance level is often taken as a measure of the strength of evidence against the hypothesis, with smaller significance levels providing more evidence against the hypothesis. Suppose, for example, the hypothesis being tested is that two populations have the same risk of chronic respiratory disease. This is called a "null" hypothesis—that is, there is no difference. If, in view of the data, this hypothesis is found to be highly improbable (that is, to have low probability of occurrence) one rejects the hypothesis (of no difference in risk of disease between populations) and assumes instead that there *is* a difference in risk of chronic respiratory disease between the two populations.

C. Specific Health Effects Studies

1. CHRONIC RESPIRATORY DISEASE (CRD) PREVALENCE

CHESS estimates adult chronic respiratory disease prevalence by means of a self-administered questionnaire which inquires whether the subject coughs and produces phlegm for at least three months of the previous year. These studies compare CRD prevalences in adjacent communities with different pollution levels, often designated "High," "Intermediate" or "Low." The Monograph reports on data gathered in the New York City and Salt Lake City areas in 1970–1971 and also includes studies from the Chicago area and five Rocky Mountain communities. CHESS monitoring stations were never present in Chicago or the Rocky Mountain communities, and exposure estimates were based on local data sources and theoretical extrapolations in these areas (see Chapters IV and V). CHESS monitoring stations only became operational in Salt Lake City in December, 1970. Attention in this investigation was confined to the four surveys, which were reviewed by Chapman et al,[1] and to New York City CHESS follow-up data [2] from 1971–1972.

The CHESS CRD questionnaire was adapted for self-administration from an interview-administered questionnaire used by the British Medical Research Council.[3] Although a similar questionnaire had been validated for self-administration in a 1971 Japanese study,[4] the

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[1] Chapman, R. S., Shy, C. M., Finklea, J. F. House, D. E., Goldberg, H. E., Hayes, C. G., "Chronic Respiratory Disease in Military Inductees and Parents of Schoolchildren." *Archives of Environmental Health*, Volume 27, Number 3 (1973), pp. 138–142.

[2] Galke, W. A., House, D., "Prevalence of Chronic Respiratory Disease Symptoms in New York Area Adults, 1972." *EPA In-House Technical Report* (June 7, 1976).

[3] "Standards for Epidemiologic Surveys in Chronic Respiratory Disease." National Tuberculosis and Respiratory Disease Association. (1969).

[4] Tsunetoshi, Y., Shimiza, T., Takahashi, H., Ichinosawa, A., Ueda, M., Nakayama, N., Yagamata, Y., "Epidemiological Study of Chronic Bronchitis with Special Reference to Effect of Air Pollution." Int Arch Arbeitsmed. Volume 29 (1971), pp. 1–27.

Monograph does not contain validating data for U.S. surveys. An internal EPA report[5] dated 1973 showed that the self-administered questionnaire detected only three of nine cases of chronic bronchitis found through interview. Survey supervisors noted that the word "phlegm" was not understood by some subjects, suggesting that educational attainment affects CRD response. However, even if the CHESS questionnaire underestimates CRD prevalence in a given community, it may give a reliable indication of the difference in CRD prevalence between two communities of similar educational attainment.

The Bronx, Queens and Riverhead, Long Island represented two Intermediate and one Low level of urban pollution in the New York City area. The Intermediate regions exceeded Riverhead in total suspended particulate (TSP), sulfur dioxide (SO_2), suspended sulfate (SS) and suspended nitrate (SN). Generally, questionnaires were given to school children who gave them to their parents to fill out. Thus, the sample is not representative of adults in general but only of parents of school children. Only 73% of Riverhead parents responded to the questionnaire which probably reflects the fact that a large number of Riverhead questionnaires were mailed to the parents rather than distributed through the children. Only white respondents who provided sufficient questionnaire data and who had stable residence histories were included in the analysis. Queens was shown to have the highest income and educational level and unpublished data showed Queens to have a larger proportion of Jews than Bronx. These facts may account for the higher CRD prevalence rates reported for the Queens than Bronx. No formal adjustments were applied for these socio-economic covariates. While smokers and non-smokers were treated separately, no covariate adjustments were made for exogenous exposure to cigarette smoke at home or work or for occupational exposure (which affected less than 1% of respondents). The statistical methods were sound. Sex- and smoking-specific prevalence rates were consistently lower in Riverhead than in Queens or Bronx, the difference being 5% typically. For comparison, smokers had prevalence rates nearly 10% above non-smokers in the same community. A linear model for categorical data[6] was used to make smoking-, age-, and sex-adjusted tests for community differences in prevalence rates, and the differences were statistically significant. A parallel analysis using severity scores for CRD confirmed the analysis of prevalence. While the statistical methods were appropriate, additional information would be helpful. In particular, confidence intervals on the prevalence rates in Table 5.2.7 (unless otherwise indicated, figure, page and Table citations refer to the CHESS Monograph) and observed and expected rates under the linear model of Table 5.2.8. would allow the reader to make specific prevalence comparisons and to verify that the linear model held for all subcategories.

Communities in the Salt Lake region provided an opportunity to study the effects of sulfur oxide (SS, SO_2) smelter emissions. Other urban pollutants, including SN and TSP, were moderate or low. Magna was exposed to intermittent smelter fumigations of SO_2 and had the highest average SO_2 and SS levels of these pollutants, and Ogden was designated Low. Aerometric copper data was not available. The questionnaire was distributed through elementary school children and mailed to parents of high school students. Response rates of 85% and 35% were found for child-carried and mailed questionnaires respectively. Although the 65% nonresponse rate to mailed questionnaires admits the possibility of serious reporting bias, the authors assure the reader that inter-community CRD differences (presumably similar) were observed for both sets of parents. Respondents were excluded for incomplete questionnaires, for a residential change within the previous two years, and for occupational exposure to irritants such as coal dust, cutting oils, asbestos, mine dust, smelter fumes, cotton dust and foundry dust. Subsequent analysis showed that the occupational exclusion gives a conservative estimate of effects attributable to pollution. All races were included, but the proportion of black respondents was trivial. No covariate measurements were made to assess religion, exposure to exogenous cigarette smoke at home or work, or racial composition, although Salt Lake City has proportionately fewer Mormons, and Magna more Spanish Americans. Educational attainment was comparable in the four communities. CRD prevalence rates reflected pollution levels faithfully, and rates in Magna (High) exceeded those in Ogden (Low) by 2–4%, depending on sex and smoking status. These differences were found to be statistically significant using the sex, smoking and age adjusted linear model.[7] For comparison, differences in CRD prevalence attributable to smoking and to occupational exposure were 10–20% and 2–8% respectively. Thus, air pollution and occupational exposure were associated with comparable increases in CRD prevalence, and personal smoking habits seemed to be a more important determinant.

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[5] House, D., "Reliability of the CHESS School and Family Health Questionnaire." EPA Human Studies Laboratory Internal Report (April 12, 1973).

[6] Grizzle, J.E., Starmer, C.F., Koch, G.G., "Analysis of Categorical Data by Linear Models." *Biometrics* Volume 25, Number 3 (September 1969), pp. 489–504.

The exposure data from the Rocky Mountain communities were least adequate. Two smelter communities, Kellogg and Anaconda, had relatively high levels of SO_2. East Helena and two non-smelter communities, Bozeman and Helena, were classified as Low. Ambient zinc, copper and lead were not measured. Nearly 85% of the questionnaires distributed by elementary school children were returned. Respondents were excluded for occupational exposure, but no residence duration requirement is mentioned. Over 97% of respondents were white. Low communities were better educated than High communities, and most occupational exclusions were from the latter, but these factors tend to reduce the apparent pollution effect. Conversely, the increased residential crowding in High communities might increase apparent pollution effects. Sex-, education-, smoking- and age-adjusted prevalence rates were statistically significantly higher in High than Low communities (Table 3.2.6). High communities had CRD prevalence rates 1–3% higher than found in Low communities (Table 3.2.5). Corresponding differences associated with smoking and occupational exposure were 10–16% and 0.1–3.6% respectively.

The Chicago studies compared urban (High), suburban (Intermediate) and clean surrounding areas of Illinois and Indiana (Low). Local SO_2, SS and TSP measurements were used, and other urban pollutants were not measured. Gary, Indiana was included in urban and may represent a special industrial pollution hazard. A CRD questionnaire designed by Julius Goldberg was administered to recruits reporting to the Chicago induction center. This population obviously differs from the previous three and contains only young male adults. Some with serious respiratory problems may have been exempted prior to induction. To be analyzed, the questionnaire had to be adequately filled out and the respondent had to have lived at his present address for at least three years. Statistically significant age-, race-, smoking-, and education-adjusted community differences in prevalence rates were found for black smokers and white nonsmokers (Table 4.2.8). However, the significance levels for black smokers and the adjusted rates in Table 4.2.7 are suspect since the linear model does not fit the data well for black and white smokers. (The "adjusted" rates in Table 4.2.7 are really expected rates under the linear model, which is a useage unfamiliar to epidemiologists.) Race and smoking specific prevalence rates tend to be 0.4–3.6 percent higher among urban than Low communities, while smoking effects are 0.3–3.5 percent for blacks and 12.4–15.1 percent for whites.

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[7] Grizzle N. E., et al., op. cit.

To summarize, these four studies demonstrate that higher adult CRD prevalence rates are associated with pollution in two urban sites and in two smelter-exposed sites with high sulfur oxide emissions. The magnitude of these differences is comparable to that associated with occupational exposure but smaller than that associated with smoking. Such differences were not seen in a 1970 CHESS study in Chattanooga, comparing communities with different nitrogen dioxide levels.[8] New York CHESS studies in 1971–1972 showed no significant differences in CRD prevalence among Riverhead, Queens Bronx and Sheepshead Bay,[9] and prevalence rates were dramatically reduced compared to 1970–1971 values. Perhaps subjects tire of the CRD questionnaire and report less symptomatology on repeated sampling. This would limit the usefulness of the CRD questionnaire as a health surveillance measurement. An alternate explanation is that decreasing CRD prevalence reflects decreasing pollution in New York.[10]

These studies demonstrate that small CRD prevalence increases are associated with pollution levels which are moderate by historic standards in urban and smelter sites. The Monograph contains no formal methods for associating these effects with a specific pollutant or for establishing a dose-response relationship. Any such inferences are tenuous, especially since the aerometric data is of dubious quality and completeness (See Chapters IV and V). The authors are to be complimented for applying newly developed and appropriate statistical methods.

2. RETROSPECTIVE SURVEYS FOR ACUTE LOWER RESPIRATORY DISEASE (LRD) IN CHILDREN

The Monograph contains data from questionnaires asking mothers to recall how many times each child under age twelve had had pneumonia, croup, or bronchitis during the previous three years. Data was also gathered on related hospitalizations and doctor visits.

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[8] Chapman, R.S., et. al., Prevalence of Chronic Respiratory Disease In Chattagnooga: Effect of Community Exposure to Nitrogen Oxides. EPA Internal Draft. July, 1973.

[9] Galke, W.A. and D. House. Prevalence of Chronic Respiratory Symptoms in New York Area Adults-1972. EPA Internal Draft. June 7, 1976.

[10] Galke, W.A. and D. House. op. cit.

These questionnaires were distributed through school children together with the 1970 Salt Lake and Rocky Mountain CRD questionnaires. Children less than one year old, those with incomplete questionnaires, and asthmatics were excluded from analysis. This last exclusion tended to minimize estimates of pollution affects (See Table 2.3.4). The sample is not a random selection from all children aged 1–12, but represents only schoolchildren and their siblings Because the data is retrospective, validation is crucial. Nurses examined medical records to document LRD (any croup, bronchitis or pneumonia) detected by questionnaire. In Ogden (Low), 70% of questionnaire-detected cases were confirmed, whereas 78% were documented in Kearns (Intermediate) and Magna (High). These differences would tend to reduce estimates of pollution effects. The corresponding figures were 88% and 75% for pooled Low and pooled High Rocky Mountain communities, which would tend to increase estimates of pollution effects.

Parents smoked less in Magna than in other Salt Lake communities (Table 2.3.3), which would minimize pollution effects. The Monograph presents a higher percentage of parental smoking in pooled-High Rocky Mountain communities (Table 3.3.2), but argues no adjustment is needed.

The monograph does not specify how age-, sex-, and socioeconomic-"adjusted" rates are computed. Since the epidemiologic interpretation is predicated on these adjusted rates, some clarification, obtained from EPA interviews, is given.

A linear model[11] containing community, age, sex, and socioeconomic main effects and no interactions was fitted separately for the three residence designations in Table 2.3.12. The "adjusted" rates in each column of this table are simply the sum of the estimated overall mean and community effect. Differences of rates within each such column are estimated community effects under the linear model. These comments may explain the anomaly that adjusted rates exceed unadjusted rates in every community, both for Salt Lake and Rocky Mountain studies. A more reasonable "adjusted" rate would be obtained by applying the total estimated linear model, including all main effects, to the actual covariate composition of each community. The "adjusted" rates given in the Monograph still provide reasonable estimates of community effects, provided the linear model used fits the data well. The Salt Lake studies give no goodness-of-fit statistic or analysis of residuals, and the model is not even specified by Table 2.3.9. Thus the Salt Lake "adjusted" rates and significance levels must be regarded as provisional. Although Rocky Mountain studies give no analysis of residuals, the goodness-of-fit statistics suggest the linear model is valid.

If one assumes the validity of the linear model used, the Salt Lake studies demonstrated statistically significant community differences in three-year croup, bronchitis, and LRD incidence rates after adjustment for sex, age, and socioeconomic status (actually educational attainment of the mother). Magna residents of three years duration had LRD, croup and bronchitis rates which exceed corresponding rates in Ogden by 10.9 percent, 9.5 percent, and 7.1 percent respectively. However, these rates did not increase in strict accordance with pollution levels and Magna residents of fewer than three years actually experienced the lowest croup, bronchitis, and LRD rates. No significant community differences were found for pneumonia or hospitalization rates.

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[11] Grizzle, J. E. et al., op. cit.

Pooled High Rocky Mountain communities had significantly higher adjusted croup rates than pooled Low communities. No significant differences (at $p<.05$) were found for LRD, bronchitis, pneumonia, or hospitalization. Those residents in pooled Low communities for fewer than three years experienced higher adjusted croup, bronchitis, and LRD rates than corresponding inhabitants of pooled High communities.

The basic observation that children of families resident in smelter-exposed communities for three years or more experience higher croup rates than those in nearby communities may be valid. However, these rates do not increase consistently with increasing pollution (Tables 3.3.A.2, 2.3.8, and 2.3.A.2), and recent migrants to High areas have lower croup rates than migrants to Low areas (Tables 2.3.8, 2.3.A.2, 3.3.A.2, and 3.3.8). These inconsistencies deserve further elucidation. The documented insensitivity of the LRD questionaire reminds us that this endpoint is no better than a mother's ability to recall a three-year illness history for each of her children and to remember specific diagnoses, such as croup and bronchitis. Finally, the conclusion in the Monograph (p. 7–9) that "increases in lower respiratory disease frequency are probably associated with suspended sulfates rather than sulfur dioxide" is tenuous at best, since no formal methods of relating health effects to a specific pollutant are described and since suspended sulfate measurements are not available in Salt Lake and Rocky Mountain communities for the years 1967–1970 surveyed by these questionnaires.

3. ACUTE RESPIRATORY DISEASE (ARD) IN VOLUNTEER FAMILIES

The Monograph contains New York ARD studies from 1970–1971. Telephone interviewers made biweekly calls to mothers of families enrolled in the study to inquire whether any family member had developed upper or lower respiratory illness in the preceding two weeks, and, if so, whether a doctor had been consulted and how many days of restricted activity had eventuated. If an individual was reported to have both upper and lower respiratory symptoms, his illness was classified as lower respiratory disease. Thus, the least ambiguous diagnostic category is "all respiratory illness." A 10 percent subsample of families who had cooperated on the CRD questionnaire was recruited for the ARD study. An eligible family had to have resided at least the past year within 1.5 miles of a CHESS monitoring site, to be white, to have one or more children age 12 or less, and to have a working phone. Priority was given to families with many preschool siblings, and in a subsequent protocol, such "priorities" were specified in writing. These priority schedules introduce ambiguity into the eligibility requirements. The major response variables were the number of respiratory illnesses per hundred person-weeks exposure (the attack rate) and the severity score, which reflected physician visits, fever, and restricted activity. The severity score scale has been criticized as arbitrary, and inversions for scores II and III in the upper respiratory column of Table 5.3.9 support this view. Table 5.3.4 (which has obvious misprints for Bronx data) shows that only 750 of 1,136 families in Riverhead participated for the full 32 weeks of study, while 887 of 1,153 families did so for Queens. Selected interviews were repeated a few days after the initial call and concordant results were obtained in over 90 percent of those previously reporting ARD and 98 percent of those previously denying ARD. This validation shows the interviews were reproducible, but it does not verify the medical content.

The authors point out that the pooled Bronx-Queens community has a higher proportion of adult smokers and of children exposed to smoke at home than Riverhead. More cooking gas was also used in Bronx-Queens. But no formal adjustments were made for these covariates. The percent of crowded families was 15 percent in Riverhead and 17 percent in Bronx-Queens, a difference the authors judged to be inconsequential. (Table 5.3.14).

The analysis of these panel studies is complicated by the fact that biweekly attack rates are statistically dependent, since the same people are repeatedly surveyed. The same comment applies to severity scores. Significance levels or confidence limits cannot be estimated without an analysis of such dependence, which the Monograph does not provide. In particular the Monograph does not specify the methods used for computing significance levels in Tables 5.3.5, 5.3.7, and 5.3.15, and the quoted significance levels are suspect. The formal statistical properties of "attack rates" and "relative risks" are insufficiently defined to allow us to calculate confidence intervals and perform significance tests, even though these quantities may be useful descriptive statistics.

Figure 5.3.1 shows that Riverhead attack rates are usually lower than either Queens or Bronx rates. It is inconsistent with the pollution hypothesis that Queens has higher rates than Bronx for 13 of the 15 surveys shown. Perhaps this reflects socioeconomic differences mentioned in the CRD discussion.

Table 5.3.6 contains ratios of attack rates with the Low community rate as denominator.

Bronx and Queens rates usually exceed Riverhead rates for lower respiratory illness and all respiratory illness, but the relation is inconstant for upper respiratory illness. This difference may be an artifact of classifying all those with upper and lower respiratory symptoms as lower. For the unambiguous category of "all acute respiratory disease," Table 5.3.6 shows the pooled Queens-Bronx rates to exceed Riverhead rates for fathers, mothers, school children, and preschool children. Table 5.3.13 divides the populations shown in Table 5.3.6 into those who have lived five or more years at their present residence (stable) and those who have moved (mobile). It is surprising that stable fathers and mothers actually experience lower attack rates in pooled Queens-Bronx than Riverhead, and this inconsistency warrants special consideration. Likewise confusing is the result (Table 5.3.14) that crowded families have lower attack rates than less crowded families.

The 1969–1970 Chicago ARD study compared Intermediate, High, and Highest Chicago neighborhoods. Twenty monitoring sites run by the City of Chicago were ranked in order of increasing 1960 TSP values. The lowest 10 were designated as Intermediate, the next five as High, and the five with highest TSP values as Highest. Such designations did not correspond to SO_2 ranking (Table 4.3.1) and SS was not measured for these sites. Families with 2–5 year old children in day care centers located near monitoring stations were recruited. The family was assigned the exposure classification of a monitoring station in the same census tract, if any, but the Monograph is unclear about exposure designations for families in unmonitored census tracts. Over 500 of the families initially enrolled participated throughout the study. Biweekly telephone interviews were used to gather data for attack rates and severity scores as in New York. Review of doctors' records documented 95.3% of telephone-survey-detected ARD.

The Highest exposure category contains more smokers and more professionals than the two other categories. The Monograph gives smoking-adjusted relative attack rates (Table 4.3.15) which show this covariate does not alter conclusions, but the method of adjustment is not presented. Although families of professionals appear at higher risk than those of non-professionals (Table 4.3.13), adjustment for this covariate was said to produce little change. The racial composition of the exposure categories is not given.

Figure 4.3.1 shows that Intermediate families experienced the lowest attack rates during 20 of 25 biweekly surveys, but the largest differences were evident during the three month influenza season. One wonders why the first three surveys were omitted in Chicago but not New York. Severity score rankings show inversions in days of restricted activity (Table 4.3.7) as in the New York study, which argues against this scoring system. The relative risk data in Table 4.3.5 shows higher ARD attack rates in Highest than in Intermediate exposure families for fathers, mothers, older siblings, nursery school children, and younger siblings. This result holds both for mobile and stable (three year residency) families (Table 4.3.11), in contrast to the New York study. The Monograph does not define Table 4.3.12 adequately. If the analyses were performed on attack rates, the significance levels quoted are untrustworthy. If by "frequency" the authors mean the proportion of families ever experiencing ARD during the study period, then use of the linear model is justified, but more explication is needed.

These two ARD studies have the advantage that health data were gathered prospectively by telephone interview, so the recall of the mother was not taxed as in the LRD studies. The quality of the health data are probably adequate, and descriptive statistics, such as "attack rates" and "relative risks" are no doubt useful guides. However, some mathematical statistical investigations to compute confidence intervals and significance tests would be a valuable addition to this methodology, especially since these problems are non-trivial. It is likely true that families exposed to high levels of urban pollution experience higher ARD attack rates than those less exposed. However, two surprising findings require further study, namely: (1) Why do residentially stable fathers and mothers experience lower attack rates in Bronx-Queens than in Riverhead? (2) Why do crowded families in New York and less educated families in Chicago appear at lower risk?

Summary statements linking specific SO_2, SS and TSP levels to excesses in ARD attack rates must be viewed with customary caution.

4. ASTHMA PANEL STUDIES

The 1970–1971 Salt Lake asthma panel studies attempt to correlate the daily proportion of panelists suffering an asthmatic attack with daily pollutant levels. The studies were complicated by practical and theoretical problems. Many relevant factors, including medication (steroids), humidity, exercise, daily temperature changes, nitrogen dioxide levels, copper levels, and exposure to smokers at home or work were not evaluated, and the study focused on TSP, SS, SO_2, SN (suspended nitrates), and temperature. Daily SO_2 measurements may be too unreliable for meaningful assessment (Chapter 3), and while midnight to midnight daily asthma rates were used, air monitoring samples were obtained from 10:00 A.M. one day to 10:00 A.M. the next, introducing a lag.

Potential panelists, recruited from families who had responded to the CRD questionnaire, or suggested by doctors or known asthmatics, were interviewed to obtain covariate and eligibility data. To be eligible, the asthmatic had to have been previously diagnosed by a physician and had to give a history of two or more episodes of wheezing and shortness-of-breath during the previous year. In addition he had to live within two miles of a monitoring site. This residency requirement was violated from time to time, and in 1975, 38 of 222 asthma panelists resided outside a 2.5 mile radius.[12]

Since a physician was not available to make the diagnosis of asthma for prospective candidates, certain individuals with unlikely asthma histories (such as elderly smokers with a sudden onset of "asthma") were eliminated. While this second level of panelist selection may have reduced the number of non-asthmatics, it introduces uncertainty as to what the exact eligibility requirements were. The monograph states only: "Highest priority for selection was given to non-smokers over sixteen years of age." In 1974, EPA staff suggested that an improved initial interview questionnaire was needed [13] for separating asthma from other cardiorespiratory disease, but these suggestions were not implemented. Asthma panelists were mailed weekly questionnaires and asked to record day by day whether no attack, one attack, or more than one attack had occurred. Some failed to return diaries, and some filled them out for the wrong week. Those who consistently failed to return diaries were eliminated from the panel, as were those who never reported an attack and those who reported an attack every day.

The 1970–1971 Utah CHESS Progress Report [14] gives summary asthma panel data indicating that mailed diaries are inconvenient. During week eight, 183 diaries were mailed out. Of these, 126 were returned on time, and 30 additional diaries were returned after telephone prompting. Ten calls were required to obtain or correct particular entries. Of the 183 diaries sent out, 156 provided "useable" data for this typical week. The mailed diary was discontinued in the 1973–1974 protocol and replaced by a weekly telephone interview to gather diary data kept by panelists at home.

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[12] Beck, M. M. and P. Carl, Bureau of Environmental Epidemiology Technical Report Number 3. Utah State Department of Social Services, Division of Health. 1975.

[13] Calafiore, D. Memorandum to CHESS Field Epidemiology Director. HSL., and Attachments, (January 31, 1974).

[14] Utah CHESS Progress Report. October 22, 1970 to December 31, 1971.

The Monograph deemphasizes covariates since no intercommunity comparisons are made. Some community differences in age, sex, education, and smoking habits are noted (Table 2.4.2).

Dropout rates varied by community. Magna, Kearns, Salt Lake City, and Ogden had respective dropout rates of 13/48, 24/55, 20/46 and 14/46 during 43 weeks of study.[15]

The measured response was the daily proportion of panelists reporting an asthma attack. The daily composition of the panels (age, sex, severity or illness) changes as panelists drop-out and are replaced. Since some panelists continue throughout the study, daily asthma attack rates are statistically dependent, which complicated the analysis.

Figures 2.4.1–2.4.4 relate mean weekly attack rates for each panel to weekly minimum temperature, weekly TSP, weekly SO_2, and weekly SS. By superimposing these graphs one can see that Ogden (Low) often has higher attack rates than Magna (High). The Monograph makes no such comparison. Conspicuously absent are corresponding graphs for Salt Lake City and Kearns.

Sample correlations for daily attack rate with daily pollutant levels are shown in Table 2.4.3. Sulfur dioxide has negligible positive correlations with daily attack rate. Correlations for TSP are positive in all sites and negative for SN and minimum temperature in all sites. Suspended sulfates are negatively correlated with daily attack rate in three of four sites. These correlations indicate that SS, SN, and minimum temperature are usually low when daily attack rates are high. Quite the opposite was observed in New York (Table 5.4.3.) where SO_2 shows negative correlations in two of three sites, SN is positively correlated in all sites, and SS is positively correlated in two of three sites. While these conflicting correlations may have descriptive value, the significance levels in Tables 2.4.3. and 5.4.3. are untrustworthy since daily attack rates are statistically dependent.

This remark applies to the multiple regression analysis (Tables 2.4.4. and 5.4.4.). Researchers at EPA and collaborators have recognized that both the daily attack rates and pollution levels are time series with autocorrelation structure, and they have begun to explore alternative analyses. Stebbings[16] noted that autocorrelations affect multiple regression parameter estimates and mentioned the need for methods which could detect lagged relationships between pollutant and attack rate.

Bloomfield[17] responded by suggesting an analysis of spectral coherence to relate attack rate and pollutant level time series Hasselblad[18] recently suggested methods based on first order Markov structure, and French et. al.[19] recently used an informal but sensible analysis to relate pollutant combinations to attack rate.

Even if daily attack rates were statistically independent, so that the significance levels in Table 2.4.4 had meaning, one would need to exercise caution when inferring that particular pollutants are associated with daily attack rate. This is because daily pollutant levels are correlated (Table 2.4.3.). Ridge regression methods[20] applied to the Salt Lake data to investigate this "multicollinearity" of pollutants show that temperature adjusted SS effects are stable. This result tends to support the hypothesis that SS may be important, but formal statements of statistical significance are not justified.

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[15] Utah CHESS Progress Report, op. cit.

[16] Stebbings, J. H. Some Problems In the Design and Analysis of Panel Studies In Epidemiology. Seminar at Princeton's Department of Statistics. October 16, 1975.

[17] Bloomfield, P. "Spectrum Analysis of Epidemiological Data." Updated reprint from the Department of Statistics, Princeton University.

[18] Hasselblad, V., "Analysis of Panel Studies." *EPA Internal Draft (June 1976)*.

[19] French, J. G., Hasselblad, V., Sharp, G., Truppi, L., "A Study of Asthma in the Los Angeles Basin: 1972-1973." *EPA Internal Draft (June 10, 1976)*.

To compute the relative risks in Table 2.4.5. (and 5.4.5.), the data from all days with minimum temperature between 30–50° F and integrated SO_2 less than or equal to 60 $\mu g/M^3$ were pooled, and the total number of attacks was divided by the total number of persons-days to obtain the rate 16.9 (Table 2.4.5.). Ratios of such numbers were termed "relative risks." The statistical properties of these relative risks require further study, since the days contribute statistically dependent data. Also no consideration is given special combinations of pollutants since the same days are used (except for days with missing pollutant data) for each pollutant. The only large increases in relative risk occurs on days with high SS and high minimum temperatures, but these relative risks are based on numerators with few person-days exposure, and the corresponding increases in New York (Table 5.4.5.) are unimpressive.

The "hockey stick" model[21] used to determine threshold is a three parameter non-linear model (attack rate intercept, threshold, and suprathreshold slope) which the authors fit by least squares. Confidence limits are not given for the estimated slopes and thresholds; nor are these appropriate since the daily attack rates are dependent and possibly heteroscedastic (i.e., with different variances). The Monograph gives no analysis of residuals, nor is the original data plotted on the fitted graphs (Figs. 2.4.5.–2.4.7.). Thus, the reader cannot assess whether the "hockey Stick" model fits the data or whether the data suggest that a threshold even exists. One such scatterplot of SO_2 data does not support the concept of a threshold[22] and it is likely that uncritical use of the hockey stick function has led to estimates of non-existent thresholds on occasion.

The New York asthma studies had similar practical and theoretical difficulties as documented in the 1970 Biannual Report.[23] Figure 12 of that Report shows 74 of 80 mailed diaries were useable, of which 14 required telephone prompting or interviewing. Eleven of 43 Bronx panelists dropped out during the study whereas the rates for Riverhead (8/38) and Queens (11/52) were smaller (Figure 10 of the Biannual Report[24]). Superimposition of the Figures 5.4.1.–5.4.4. shows that Riverhead often has lower weekly attack rates than Queens, but such data is not given for Bronx. Preliminary analysis of 1971–1972 New York asthma panels using the same statistical methods as in the Monograph suggest that SN is a more important risk factor than SS. The Monograph gives no relative risk calculations for SN, and SN was discounted in correlation and multiple regression analyses in 1970–1971 Salt Lake and New York studies. Relative risk tables from the 1971–1972 New York study confirm the 1970–1971 association of SS with daily attack rate, but the effects of SN cannot be disentangled since SN is highly correlated with TSP, RSP (respirable suspended particulates), SS, and SO_2 in the 1971–1972 study. Comparison of the conclusions of these two New York studies highlights the difficulty of associating a specific pollutant with asthma attack rate, but both studies show attack rate is associated with daily urban "pollution."

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[20] Smith, K. J. C., "A Ridge Regression Analysis of the CHESS Studies; Salt Lake Asthma." Undated EPA Internal Draft.

[21] Hasselblad, V., Creason, J. P., Nelson, W. C., "Regression Using Hockey Stick Functions." EPA-600/1-76-024 (June 1976).

[22] Demill, K. M., Wride, W. P., "Technical Memorandum 76-2." Kennecott Copper Corporation, Operations Research, Salt Lake City.

[23] Pravda, M., "Community Health Effects Surveillance Studies: New York City." Internal Biannual Report to EPA (December 1970).

[24] Ibid.

These panel studies suffered from several practical and theoretical deficiencies. Panelists were not examined by a physician and eligibility requirements were somewhat obscured by a "priority" system of secondary selection. Numerous factors known to precipitate asthma attacks were ignored. The analyses failed to consider autocorrelation in the asthma attack rate and daily pollution levels, and the authors did not present spectral or lag analyses. The significance levels presented are untrustworthy, since the attack rates are dependent. The statistics used have descriptive value, but the patterns of correlation between pollutants and attack rate are strikingly discordant in Salt Lake and New York. It is disturbing that Ogden (Low) often has higher attack rates than Magna (High), and this observation requires further investigation. Although SS may well precipitate asthma attacks, the hockey stick model used to estimate thresholds was not shown to fit the data. Tentative findings of the 1971–1972 New York asthma study highlight the difficulty of relating asthma attack rate to a specific pollutant.

This commentary emphasizes limitations of the analytical methodology and problems in data collection because these topics are scarcely mentioned in the Monograph. The panel strategy is nonetheless an appropriate tool for studying the effects of pollution on selected high risk populations, and the statistical methods used provided considerable insight in exploring possible relationships between pollutants and asthma attack rates. The fact that time series methods were not used or that theory could not provide formal inference (without further research) for statistics such as the "relative risk" should not obscure the descriptive and exploratory merits of the methods used.

5. CARDIOPULMONARY SYMPTOMS IN ADULT PANELS

These 1970–1971 New York studies attempted to associate symptom aggravation in high risk elderly panels with daily pollutant levels. Since these studies were similar to the asthma panel studies, they shared similar practical and methodological problems. Figure 14 of the Biannual Report [23] shows that recruitment varied by community. Riverhead contacts came from trailer parks and from recreation and golden age clubs whereas Queens and Bronx participants were contacted on park benches or through the New York Housing Authority. It is hardly surprising, therefore, that Riverhead (Low) participants were generally younger and healthier than those from Queens and Bronx (Table 5.5.A.1.) Candidates were interviewed and questionnaire information was used to classify them as well, heart, lung, or heart-lung panelists. No previous or concurrent physician diagnosis was specified in the 1971–1975 protocols (although the Monograph summary on page 5–104 mentions physician diagnosis). Eligible candidates had to reside within 1.5 miles of a monitoring site and to be 60 years of age or more. In later studies, younger panelists were accepted and some candidates were found outside the 1.5 mile monitoring radius, especially in Riverhead.

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[23] Ibid.

Substantial numbers of enrollees dropped out during the study, many because they were too sick, had difficulty filling out the weekly diary, or just found the study bothersome (Figure 16 of Biannual Report[26]).

The Monograph states that dropout rates exceeded 50% in Bronx and Queens and approached 30% in Riverhead.

Many panelists failed to return weekly diaries. Figure 15 of the Biannual Report[27] shows that only 49 of 86 Riverhead panelists provided useable diaries for the week November 22–28, and corresponding fractions for Bronx and Queens were 38/99, and 9/59. The fraction of useable diaries for the heart, lung and heart-lung panels was usually even smaller. Thus Bronx, Queens and Riverhead yielded respectively 24/47, 18/40 and 10/13 heart-lung diaries, 14/31, 6/21, and 20/26 lung diaries and 26/59, 19/52, and 27/39 heart diaries. Mailed diaries were replaced by telephone interview in the 1973–1974 protocol.

The high dropout rates and poor weekly diary response rates limit the generality of these studies since the data was generated by a self-selected population. This fact also complicates community comparison.

Panelists were asked to specify daily whether symptoms were "worse," "much worse," "the same," "better," or "never present" and daily aggravation rates were computed as the sum of "worse" plus "much worse" divided by all participants that day. (The "much worse" category was eliminated in subsequent protocols.) Table 5.5.2 shows that Bronx and Queens aggravation rates are usually higher than Riverhead rates, but the authors do not ascribe these differences to pollution since Riverhead is known to contain younger, healthier panelists.

Figures 5.5.3–5.5.6 relate composite weekly symptoms aggravation rates to weekly SO_2, TSP, SS, and SN for the Riverhead and Queens heart-lung panels. The aggravation rate seems to rise and fall with SS levels. No such graphs are given for Bronx nor for well, heart and lung panels.

Table 5.5.4 shows that SS is positively correlated with daily symptom aggravation in the well and heart-lung panels, but the stated significance levels are untrustworthy since daily aggravation rates and pollution levels are each autocorrelated. Multiple correlation analysis confirms that temperature adjusted SS is associated with symptom aggravation, especially in the heart-lung panel (Table 5.5.6), but these significance levels too can only be taken as qualitative indicators. Because the daily pollutant levels are highly correlated (Table 5.5.5), specification of a particular pollutant for particular concern is speculative. However, it is impressive that other pollutants have little explanatory power after temperature and SS adjustment whereas SS still explains substantial variation in daily aggravation rate after adjustment for temperature, SN, TSP, and SO_2. Table 5.5.3 shows that daily SS was strongly positively correlated with shortness of breath aggravation in six panels and strongly negatively correlated in none. These figures are derived from Table 5.5.A.3

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[26] Ibid.
[27] Ibid.

which shows that the correlation was strongly positive in all three heart-lung panels, in two of three heart panels and in one lung panel (Queens). Temperature specific relative risk calculations (Tables 5.5.7–5.5.9) also suggest that SS is associated with increased symptom aggravation rates, especially in the heart-lung panel on warm days. Such a table is not presented for SN. All these methods suggest an association between SS and symptom aggravation rate in heart-lung panels. It would be interesting to know if the SS data indeed exhibited a threshold effect and fit the hockey stick model in Figure 5.5.8.

The severe dropout rates and low weekly diary returns (especially for the heart-lung, heart and lung panels) raise important questions as to the type of respondent and the meaning of the response "worse." The statistical methods have the limitations mentioned for asthma panels. Moreover, a subsequent New York 1971–1972 study[23] failed to confirm the dominant importance of SS but did find that SS, SN, SO_2 and RSP were associated with symptom aggravation of the well panels. (This study did not use the same analysis as the Monograph and, in particular, did not include temperature adjusted multiple regression or temperature specific relative risk calculations.) Nonetheless, the 1970–1971 data suggest an association between symptom aggravation rates and various pollutants, especially suspended sulfates.

6. VENTILATORY FUNCTION IN SCHOOL CHILDREN

The Cincinnati study of ventilatory function in school children preceded CHESS. Children from schools in an industrial valley of Cincinnati were compared with children from schools in a non-industrial river valley on the east side of the metropolitan area. Two upper-middle white, lower-middle white and lower-middle black schools were selected from each valley. Air monitoring stations within three blocks of the schools showed that seven month average TSP values were from 18 to 32 $\mu g/m^3$ higher in the industrial valley than in the non-industrial valley, but corresponding differences for SS, SN and SO_2 ranged from 0.1 to 1.1, 0.1 to 0.8, and 0.6 to 10.4 respectively (Figure 6.1.1). Thus, the industrial valley had more TSP than the non-industrial valley, but its levels of SS, SN, and SO_2 exceeded those in the non-industrial valley by very small margins. Ventilatory function was measured as the forced expiratory volume at three quarters second (FEV .75), and height, sex, and race were noted to make adjusted FEV .75 comparisons.

The study was confined to 394 second graders who participated in weekly measurements during November 1967, February 1968 and May 1968. These students represented 93 percent of second graders in the classrooms selected. Mothers were interviewed to obtain socio-economic data. The educational attainment of fathers was similar for corresponding schools in the industrial and non-industrial valleys (Figure 6.1.2).

Figure 6.1.3 shows that average height adjusted FEV .75 in "clean" schools exceeded that in "polluted" schools in all three months for lower-middle whites and in two of three months for upper-middle whites. Blacks had consistently lower FEV .75 values, and a "pollution" effect was only seen among blacks during one of three months. The absolute differences in average FEV .75 were roughly 40–120 milliliters (or less than 10%) in most cases. Table 6.1.5 presents a multivariate analysis of variance which allows one to test for community effects adjusted for a possible month effect and for the covariates height, sex, race, and social class. The dependent variable for each child was his vector of three monthly average FEV .75 values. No test for a community effect (industrial valley versus non-industrial valley) was performed, but the significance levels given suggest that community differences exist. The conclusion that "suspended sulfates exerted the strongest influence" (pages 6–7) is unwarranted in view of the high correlations commonly found among these pollutants. Nonetheless, these studies support the notion that FEV .75 is 3–10 percent less among white second graders in the industrial valley than among those in the non-industrial valley.

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[23] Stebbings, J. H., Hayes, C. G., "Panel Studies of Acute Health Effects of Air Pollution I. Cardiopulmonary Symptoms in Adults." Environmental Research Volume 11 (1976), pp. 89-111.

The 1970–1971 New York ventilatory study included children ages 5 to 13. Schools were situated within 1.5 miles of CHESS air monitors, and Riverhead, Bronx, and Queens were represented by three schools each. Only white children were eligible for analysis.

A new electronic spirometer, the National Gas Cylinder (NGC), exhibited serious drift (perhaps 350 milliliters). This problem was detected by field teams who had difficulty reproducing measurements and who made several trips to the manufacturer for adjustments. The June 1971 Progress Report [29] gives an account of difficulties with the spirometer, and the Assistant Commissioner of the New York City Department of Health expressed serious reservations about the reliability of those measurements in a January 18, 1972 letter to the Acting Chief of the EPA Epidemiology Section.[30] It is possible that drift of this magnitude biased the results, since one community may have been systematically subjected to a spirometer with extreme drift (especially if drift varied in phase with the rotation of spirometers through communities). Even if rotation of the spirometers among communities distributed drift equally, the variability of the observations is greatly increased by random distribution of drift, since the community effects (60 milliliters or less) are much smaller than the drift. The NGC spirometer was replaced in late 1971 by a bellows-type spirometer described in the May 1972 CHESS protocol. However, the NGC spirometer was used throughout the 1970–1971 study reported in the Monograph.

The 1970–1971 protocol instructs investigators to "deduct one inch for stacked heels for those girls wearing such shoes." In the 1972–1973 protocol this height adjustment was reduced to ½ inch.

No data were presented to compare families of children studied in Riverhead, Queens, and Bronx, but the age distribution and parental smoking habits were said to be similar. Income and educational attainment were said to decrease in the order Queens, Riverhead, Bronx. The Monograph contains no comparison of children's smoking habits in these communities; this covariate may be relevant since statistically significant differences were found only for older children.

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[29] "New York City CHESS Progress Report." (June 1971).

[30] Bergner, Dr. L. (Assistant Commissioner for the Department of Health, New York City), Letter to Dr. Douglas L. Hammer, Acting Chief, Epidemiology Section, EPA (January 18, 1972).

Figure 5.6.1 shows that male height and age adjusted FEV .75 values from Riverhead were intermediate between Queens and Bronx values for three of four test periods. For females, the Riverhead values exceeded Bronx and Queens values in each test period, but the differences were usually less than 50 milliliters. Table 5.6.5 show that Riverhead height adjusted FEV .75 values were largest during one of four test periods for young males, three of four for older males, one of four for young females, and three of four for older females. Thus these differences were inconstant, and even for older females, the average difference between Riverhead and Queens was only 42 milliliters (about 2.4%). Table 5.6.6 is puzzling since it includes a degree of freedom for "ethnic differences" not described in the text. Perhaps blacks were included in this analysis. The multivariate analysis of variance used in Table 6.1.5 is more appropriate than averaging over all test periods as in Table 5.6.6. However, the analyses for individual test periods in Table 5.6.6 show statistically significant differences for older males and females.

The Cincinnati study demonstrated small (less than 10%) differences in FEV .75 between white children in schools located in a non-industrial valley and those in schools in an industrial valley. For New York, small, inconstant differences were found between Riverhead and Queens-Bronx only for older (9–13 years old) children. Preliminary analysis of 1971–1972 New York CHESS winter and spring data obtained with a bellows-type spirometer shows that older Riverhead children had statistically significantly higher FEV .75 values than Bronx children in winter and statistically significantly lower values in spring.[31] In view of these findings, the problem of spirometer drift, and the possibility that older children in Bronx and Queens smoke more than in Riverhead, one must be cautious in linking New York pollution effects with ventilatory differences.

7. OTHER CHESS STUDIES

CHESS has conducted two types of studies not found in the Monograph. The "Episode Study" measures rates of discomfort (cough, shortness of breath, restricted activity, and eye, throat and chest discomfort) during control periods and during air pollution episodes. A 1973 report [32] shows higher rates of cough, chest discomfort and restricted activity during episodes of high air pollution. "Pollutant Burden" studies are designed to quantitate the levels of metals and other pollutants found in human tissues and to relate these levels to exposure history. Scalp hair was collected from families participating in ARD studies, maternal hair, blood, cord blood, and placental samples were obtained from willing mothers, and various tissues were obtained at autopsy from pathology laboratories.

D. Summary Assessment of the Population Studies

This assessment is made from the point of view of an epidemiologist. More global judgments, made in consideration of the quality of both epidemiologic and aerometric data, are found in Chapter III.

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[31] Chapman, R. S., Hasselblad, V., Burton, R., Williams, J., "Air Pollution and Ventilatory Function." *EPA Draft* (April 8, 1975).

[32] †Nelson, C. J., Shy, C. M., English, T., Sharp, C. R., Andleman, R., Truppi, L., Van Bruggen, J., "Family Surveys of Irritation Symptoms During Acute Air Pollution Exposures." Journal of the Air Pollution Control Association, Volume 23, Number 2 (February 1973), pp. 81–90.

No formal methods are used to link specific pollutants with specific health effects in the CRD, LRD, ventilation, and ARD studies. If a demonstrated health difference between communities cannot be explained in terms of imbalances in known covariates, it is generally ascribed to pollution. The CRD studies convincingly demonstrated small increases in the prevalence of productive cough in polluted urban and smelter sites. The retrospective LRD studies may have demonstrated higher croup and bronchitis rates in children in polluted smelter communities, and the prospective ARD are rather more convincing in demonstrating an increase in acute respiratory disease in polluted urban settings. The Cincinnati ventilation study demonstrated small differences in FEV .75 between white second graders attending schools in industrial and non-industrial urban valleys. If the aerometric measurements had been entirely accurate and reproducible during these studies, it might be safe to conclude that health effects had been demonstrated in association with known patterns of pollution. Unfortunately, this was not the case. It is not possible to know which specific pollutants, if any, or what concentrations of any suspect pollutants, were responsible for the health effects. The health effects data provide at most a rough guide for making general judgments about probable health effects in other communities with similar pollutant sources, meteorology and population composition. However, even though the aerometric data are of poor quality, the studies appear to demonstrate some health effects of air pollution at concentrations which might possibly be moderate (lower) compared with some high urban levels of the early 1960's. In this light, the data in the CHESS study provide no support for those who would significantly relax current standards; on the other hand, neither do they support a need for more stringent standards. Thus, the CHESS studies have proved to be valueless for assessing or supporting setting of quantitative regulatory standards which was a goal of the program.

The methodology used in the panel studies (asthma and cardiopulmonary) attempts to disentangle the effects of the several pollutants. The multiple regression and relative risk calculations are interpreted as implicating suspended sulfates, particularly in the Salt Lake asthma and New York cardiopulmonary studies. While this interpretation appears reasonable, these formal methods do not provide logically compelling evidence that SS, or indeed any of the measured pollutants is of dominant importance. Despite the many practical and methodological difficulties of these studies, they support the belief that asthma attacks and cardiovascular symptoms occur with greater frequency when the air is polluted.

These findings may appear overly critical especially since CHESS pioneered many research techniques. However, this report complements the CHESS Monograph, which often fails to apprise the reader of practical or theoretical problems encountered in this research. These remarks are meant to aid in the assessment of the validity of the conclusions presented in the Monograph and to assist researchers performing similar studies and encountering similar difficulties. This endeavor was greatly assisted by hindsight and by the splendid cooperation and self-examination of investigators both inside and outside the Environmental Protection Agency.

E. CHESS CURRENT STATUS

1. GENERAL

In the process of interviewing EPA personnel concerning CHESS background, a good deal of information was obtained as to present and future plans for the program. Many other program and management ideas were also offered by the EPA personnel.

The CHESS program no longer officially exists within EPA except as a historical reference point. Administrator Train on April 9th committed to have all data from the program analyzed by mid-1977. However, the effort within the Health Effects Research Laboratory directed at processing the several years of data remaining (1972–75) unanalyzed from the CHESS studies is progressing slowly. A forced change of computers (see below) caused major delay. In addition, the investigative team sensed ambivalence as to how much effort is justified. Discussions with EPA Headquarters personnel indicated that, in keeping with the Administrator's commitment, the analysis is of sufficient importance in its own right as well as to continuing programs to warrant early completion. Yet, from discussions at Research Triangle Park, it can only be concluded that many would rather spend resources initiating new projects or refining CHESS methodology. Perhaps this is just as well, since there is serious doubt that the analysis even when completed will ever be sufficiently credible to support the stated objectives of the program. Any results from the final CHESS analysis may be examined with suspicion since the doubt concerning the reliability of aerometric measurements and the accuracy and acceptability of health measurements which evolved following the first CHESS report will affect any further reports from this same program. The past loss of experienced personnel has impaired the long term research effort required by CHESS objectives and has hurt morale among the remaining researchers.

The investigative team found that the disorganized state of affairs described above is compounded by the fact that the Health Effects Research Laboratory still lacks key personnel in the health research field. The Laboratory Director has been actively seeking persons to fill several key positions, but without success.

Several personnel problems continue to frustrate members of the Population Studies Division, of the Health Effects Research Laboratory. An impending retirement leaves the Division without leadership in a period when long range plans are to be reformulated. Members of the Division wonder, in view of recent investigations including this one, whether yet another reorganization is soon to come, and many regard this organizational instability as an impediment to sound work and career development. Most believe that Population Studies staffing is inadequate in relation to program funds. This disproportion requires that most real work be done by contractors. Not only are RTP staff deprived of the incentive of planning and executing their own studies, but they lack time and travel funds to monitor the contracts satisfactorily. The Population Studies Division responds to special regulatory needs (e.g. sulfate studies) and to unforseen events such as the demand for assessment of Kepone effects in Hopewell, Virginia. While these situations and demands might form the basis of a unified program in the future, at present they are regarded as "fire-fighting" distractions.

The team found strong evidence of a continuing lack of coordination between field and Headquarters and insufficient coordination among regional programs, Environmental Research Center Laboratories, contractors, other Federal agencies studying health effects of air pollutants, and Headquarters, not only in total program objectives but also in program coordination of quality control, sample collection and analysis, and standardization of health effects data collection tools.

2. STATUS OF ANALYSIS

Schedules[33] for analysis of CHESS data show that CHESS health data were collected from 1970 through 1975 for asthma panels, cardiopulmonary panels, and ventilatory function panels. The last surveys for acute respiratory disease (ARD), and chronic respiratory disease (CRD), and acute episodes took place in 1973, 1974, and 1975 respectively. CHESS surveys were completed for 25 asthma panels, 12 cardiopulmonary panels, 28 ventilatory function panels, 15 ARD, 12 CRD, 8 episodes and 8 acute lower respiratory disease panels during this period. The Monograph reported on only eight of these panels conducted in the 1970–1971 New York and Salt Lake studies. (The Rocky Mountain, Chicago, and Cincinnati studies contained in the Monograph were not CHESS studies.) Thus, CHESS generated only a portion of the data analyzed and reported in the 1974 Monograph, and the Monograph reports on only a small fraction of CHESS data.

The present analysis of the studies proceeds in steps. First, the survey data is edited for computer processing and subjected to preliminary statistical analyses. Then an epidemiologist writes a draft on the basis of the preliminary statistical analyses of health and aerometric data. Other analyses may be done if judged necessary by the epidemiologist or statistician. EPA staff have tabulated the fraction of surveys subjected to preliminary statistical analysis and the fraction for which a preliminary draft has been written.[34] Drafts exist for 6 of 8 episode and 7 of 8 LRD panel studies. Drafts have been written for 7 of 15 ARD and 8 of 12 CRD studies, but no CRD drafts have been written for survey years 1973 or 1974. By comparison, asthma, cardiopulmonary and ventilatory function analyses are far behind schedule. Of 28 ventilatory surveys, 10 have undergone preliminary analysis, and 8 drafts have been written (as of June 28, 1976). Of 25 asthma surveys, nine have undergone preliminary analysis and nine drafts have been written, and of 12 cardiopulmonary panels, two have been analyzed and two drafts written. These figures substantiate the degree to which the CHESS program has fallen far behind in analyzing and writing up survey data (61 data sets are yet to be written up).

The figures quoted above indicate that a major bottleneck in the analysis of survey data has been the preliminary editing and statistical processing. It should be noted that EPA had little or no control over two disruptive events which retarded preliminary analyses by a year or more. GSA ordered a change of computer from IBM to Univac in August 1974 as part of a general government policy related to competitive bids. Both hardware and software conversions were difficult, and most programs had to be completely rewritten. Compounding this problem was the need to rely increasingly on outside data processing contractors, since increases in EPA staff needed to meet the increased data load never materialized even though verbal commitments had been given to the laboratory directors. GSA contracting procedures required two changes in data processing contractors between 1972 and 1974. Other problems impeded the preliminary statistical analyses. The loss of key personnel imposed new scientific and administrative burdens on remaining statisticians and epidemiologists. Moreover, responsibilities of the Statistics and Data Management Office were broadened during this period to include projects with the Toxicology and Clinical Studies Divisions as well as special tasks, such as preparing data tapes in reponse to outside requests for EPA data. CHESS analyses (Population Studies Division) now account for about half the Statistics and Data Management Office work load. However, the most important delays in the preliminary analysis are attributable to the forced computer change and to problems with outside data processing contractors.

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[33] Unpublished tables giving dates of CHESS data collection prepared by Dr. Dorothy Calafiore, EPA/RTP.

[34] Unpublished tables showing chronology of survey data analysis and draft writing prepared by Drs. Carl Hayes and/or Kathryn McClain (June 28, 1976), EPA/RTP.

The epidemiologists charged with writing a draft monograph must await receipt of aerometry computer output and biometry output. Epidemiologists interviewed attributed delays to the failure of these preliminary analyses to arrive and to subsequent changes in aerometric values used in the manuscript. Other problems retard the epidemiologists once preliminary analyses are in hand. To begin with, the Population Studies Division has lost many of the important early authors or researchers within CHESS. It is hard for an epidemiologist, not familiar with the background and history of the data collection and faced with two computer outputs, to assess the quality of the data and to obtain specific scientific guidance.

Morale is low, and this may be due in part to the loss of key personnel, to investigations of the CHESS program, and to organizational instability affecting Population Studies. Furthermore, during the past year, epidemiologists have been encouraged to pursue competing scientific interests, and they have had to shoulder administrative burdens associated with increased reliance on external contractors and to meet special tasking such as the Kepone Task Force.

It was interesting to find that several epidemiologists interviewed complained that the current team structure for analyzing survey data does not function well without a strong authority to resolve scientific and scheduling conflicts between epidemiologists and statisticians. While these factors and lack of staff have not seriously impeded the drafting of CHESS reports until now, they may become pressing problems as the backlog of preliminary analyses clears the new computer system in the near future.

The continued delays in analyzing CHESS data have had several adverse effects. Contractors gathering survey data and panelists have been embittered and demoralized by lack of data and feedback from EPA. The failure to provide contractors with timely aerometric and health data summaries stifled local initiative in analyzing the data. Thus, the CHESS program did not benefit fully from local field level insights as to local pecularities of the survey and populations or from comparisons with independent local air pollution measurements and data analysis.

3. RECENT PLANNING DIRECTIONS OF THE POPULATION STUDIES DIVISION

The following comments are largely speculations and impressions based on interviews with EPA staff.

CHESS data acquisition ended in 1974–1975 when OMB did not approve questionnaires needed for the study. Had OMB approved the forms, however, it is likely that 6 asthma, 6 ventilatory function, 2 LRD and 2 CRD surveys would have taken place in 1975–1976.[35] Instead the Populations Studies Division worked on old CHESS data and made several proposals for non-CHESS studies to be run on contract. One of these is a cohort study of ventilatory function in adolescents which uses a CHESS endpoint (measured variable) but does not use a cross-sectional CHESS replicate population. Another uses the CHESS ARD endpoint to study the effects of peak NO_2 values. One study entitled "A study to Determine the Health Effects Associated with Emissions from Coal Combustion and Coal Gasification" uses the CHESS ARD and FEV .75 endpoints to study the impact of coal combustion and gasification in local populations (Hair, blood, and urine samples are also obtained to assay for products of combustion and gasification). Other proposed studies do not use CHESS endpoints. These include: (1) a study of mortality patterns in Montana, where excessive cancer mortality has been noted, (2) a general household health survey given to members of a community located near a new sewage treatment plant, (3) a study of trace metal burdens found in the hair, blood, and urine of people living near non-ferrous smelters, and (4) an evaluation of hyperactivity and cognitive function in children with asymptomatic lead burdens. These proposals build on CHESS experience, but they do not embody any continuation of CHESS surveillance. However, only one study plan and questionnaire was approved by OMB at the time of this investigation. The continued resistance by OMB to approve new study forms and questionnaires is a great frustration to the researchers. There was a strong feeling evident that this resistance stems from a misguided assessment of scientific merit as much as from a Presidential concern for the rights of privacy.

The Scientific Advisory Board (SAB) has fallen short of EPA staff expectations. The staff members had hoped to work closely with SAB to formulate and refine new proposals. Instead, the SAB has provided only formal criticism, expressed in public meetings attended by press and industry. This is a time when the EPA staff needs new leadership from a Director of Population Studies and from close informal working relations with the SAB.

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[35] Table of proposed CHESS studies for 1975-1976 prepared by Dr. Carl Hayes, EPA/RTP.

VII. CURRENT CHESS STATUS AND FUTURE PROGRAMS

A. RETROSPECTION

It is always easier to look at the past and detect mistakes than it is to look forward and avoid them. There are lessons which can be learned from the research which produced the CHESS Monograph as well as from the efforts to process the balance of the CHESS data which remain unanalyzed and unpublished.

This investigative report supports much of the criticism of the CHESS Monograph as developed by other earlier and independent examinations. For example, a report prepared for the Federal Energy Administration in 1975 [1] describes the use of the unvalidated version of the British Medical Research Council questionnaire as limiting the reliability of the health effects analysis in programs utilizing this health indicator. The Subcommittee's investigation noted this same defect. Questions regarding the analysis of the data on asthma attacks indicated serious discrepancies. In the report to FEA, however, the significance of the errors in the aerometric data which are detailed in the Subcommittee's investigation was not fully recognized. In their review of the CHESS Monograph, the EPA Science Advisory Board (SAB) identified many of the same problems noted by the investigative team, again primarily in the epidemiological areas. In the SAB, or so called Whittenberger, Report [2] other deficiencies included: limited population sampling control; shortcomings in the methods used for assessment of past air pollution levels; variations in sample populations which limit comparison of communities; high drop-out rates in asthma panels; inadequate consideration of temperature as an important variable in consideration of asthma attacks; and serious concern about the problem of gaining information on individual exposure to pollutant levels. All of these points and others are confirmed by the Subcommittee's investigation.

As noted in the legislative history of this report (Appendix B), other independent investigators also had offered criticism of the CHESS Monograph during the brief period of peer review which occurred prior to publication and this criticism also appears to be well founded for the most part. In separate talks with researchers who had either participated in some phase of CHESS or had reason to follow the progress of the CHESS investigations and review of data samples, the Subcommittee investigators had occasion to gain separate confirmation of many of these same concerns about the validity of the instruments, questionnaires, and methods used for collecting data as well as the methods of analysis.

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[1] Preliminary Report. A Critical Evaluation of Current Research Regarding Health Criteria for Sulfur Oxides. Technical Report Prepared for the Federal Energy Administration. Tabershaw/Cooper Asso., Inc. April 11, 1975.

[2] Review of the CHESS Program. A Report of a Review Panel of the Science Advisory Board—Executive Committee, March 14, 1975.

Thus, the conclusions contained within Chapter III of this report are not exceptional in their general tenor. However, the serious errors in the aerometric data and the verified significant effect of the poor quality control during the early stages of the CHESS air monitoring, measurements and analyses efforts are identified more precisely for the first time by an outside investigation.

B. CURRENT

Moving from the historical perspective, an appropriate question to be asked is whether the errors suggested in other critiques and confirmed in greater detail by the investigative team are being adequately addressed in the current and planned Environmental Protection Agency's air pollution/health effects programs.

It was of interest, first, to determine the approximate status of the CHESS data which remain unanalyzed and to ascertain whether these data will suffer from the same or other discrepancies as the data presented in the 1974 CHESS Monograph. As is documented at the end of the last chapter (VI), in discussions with EPA personnel at Research Triangle Park, the investigative team determined that there still remains a considerable amount of analysis to be completed. The impressions gained from these interviews was that it would be at least until the summer of 1977 before the final assembly of data and examination for potential analysis and publication would be possible.

However, as noted earlier in the report (Chapter VI), a number of draft studies were completed at the time of the visits to RTP. For example, draft reports have been prepared for 6 of the 8 remaining episode type health studies and for seven of the 8 remaining lower respiratory disease studies. Seven of the remaining acute respiratory disease studies have been prepared and 8 of the remaining 12 chronic respiratory disease studies are in hand. No draft of the data on chronic respiratory disease studies appears to be ready for the survey years 1973 or 1974. Analyses of a number of other health effects studies have not been initiated.

The general impression is that there is still considerable effort required for the basic transfer of field data to computer tapes for analysis. Unfortunately, serious reservations are retained by the investigative team about some of these data since some of the same criticisms about the techniques used to collect the health effects information in the CHESS Monograph continue to apply to some of the data accumulated after 1971.

The establishment of a more vigorous quality control system appears to have improved the collection of aerometric data after 1974. The aerometric review (Chapter IV) points out that CHESS instrumentation, as used in the CHESS studies, did not consistently generate valid, reliable data in the range of the National Ambient Air Quality Standards. Thus, it is likely that no amount of effort on analysis of CHESS data would achieve the desired objectives. There is doubt that adequate meteorological support is being provided. Further, as noted in other sections of this report, there does not yet appear to be an adequate systematic planning effort to insure the full participation of all research components.

C. FUTURE

Since sulfates were identified within the CHESS monograph as being a pollutant requiring an immediate increased priority of investigation, the investigative team attempted to determine the status of work on this pollutant. Mr. Train had indicated during testimony before the joint hearing on April 9, 1976, that a five year plan for study of sulfates was available. Actually, it was found during the investigation in the summer of 1976 that the sulfate plan was still in draft form although passing through a second iteration. There was some indication that even now there is not a full appreciation of the need for planning input with regard to quality control, air monitoring, instrument use planning, structuring of health effects data collection, processing of data, analysis and publication scheduling. The required level of cooperative preplanning does not seem to be present. In a letter to the chairman of the Subcommittee on the Environment and the Atmosphere (undated) in May, 1976, Mr. Train summarized EPA's projected research program on sulfates.

In measurement and monitoring, the emphasis in the draft plan is placed upon the development of reliable analytical and sampling techniques and instrumentation to support laboratory and field measurements of sulfates and sulfur compounds; the development of quality assurance programs; data audits, and providing technical support. The ongoing research and near-term research is aimed at increased data collection on sulfates with emphasis on measurement methodology, instrument development and field tests. Emphasis is to be placed also on the development of reliable models to predict sulfate concentrations and precursor emissions over long distances. The plan indicates a recognition of the need for instrument and field tests.

A continuation of the concept that more data on the health effects of sulfates are needed is reflected in an intention to expand emphasis on the toxicological, epidemiological and clinical studies on the effects of sulfates. The plan includes a recognition by EPA of the difficulty of conducting epidemiological studies, particularly in correlating ambient pollutant (sulfates) concentrations with health effects.

With the exception of the particular emphasis on sulfates, these objectives are essentially the same as the objectives cited as necessary upon the initiation of the original CHESS studies. If these objectives are to be achieved in the near future, it will be necessary for EPA to avoid the errors of CHESS. It is not clear either from the proposed programs or from discussion with individuals who will be implementing these programs that some of the basic errors committed during the CHESS studies will be corrected before such field, air monitoring, and epidemiological studies are continued with different pollutants. Certainly, the manpower problems have not been resolved.

In the aerometric area, the CHAMP aerometric measurement and analysis is entering a new phase of development. It is essential that the aerometric measurement and analysis errors detected during the CHESS time period be eliminated as the CHAMP effort is expanded and greater emphasis is placed upon this program. The CHAMP instruments, when verified, may be capable of identifying reliable differences in absolute air pollutant levels but the instruments will be pushed to their limits of sensitivity and will require constant attention by skilled technicians. New instruments just developed may be able to meet the ultimate requirements of the air pollution health effects program.

A sound program of development and testing (verifying) questionnaires and other approaches to epidemiological research also must be mounted and completed before another CHESS-type program is initiated. Completion of both phases of such a program to provide the tools and techniques for a sound health effects program might require up to 2 years and several million dollars. If this work is not carried out, progress in the area is doubtful.

APPENDIX A

A RECAPITULATION OF THE AEROMETRIC AND METEOROLOGICAL FINDINGS OF THE INVESTIGATION AS THEY RELATE TO SPECIFIC SECTIONS OF THE CHESS MONOGRAPH AND THE HEALTH FINDINGS

A. INTRODUCTION

This section contains citations of errors and omissions found in a careful review of the CHESS Monograph which show that the use of aerometric and meteorological data in correlation with health effects end point measurements can easily mislead the reader of the CHESS document into inferences which are not wholly or even partially supported by the data in the report. Page, paragraph, and figure references are to the 1974 CHESS Monograph.

Since an important application of the aerometric data is to determine correlations with health effects, any errors or overusage of aerometric data based upon estimates or improper measurements will obviously reduce or negate the value of any health effects correlations which are attempted. This misusage or overusage of aerometric data will be particularly damaging as the extension of the conclusions is made in an attempt to discover possible threshold effects.

B. CRITIQUE

1. Prevalence of Chronic Respiratory Disease Symptoms in Adults: 1970 Survey of Salt Lake Basin Communities

Observed concentrations for only one year have been used to crudely estimate concentrations of sulfur dioxide and suspended sulfates relating to a 4–7 year exposure. The 1971 observed annual average concentration of sulfur dioxide was used with the 1971 emission rate from the smelter to obtain a ratio that was then multiplied by emission rates for other years to estimate concentrations for the other years. The estimated sulfur dioxide concentrations were then used in a regression equation based on a 1971 relationship to estimate suspended sulfate concentrations. Possible changes in meteorological conditions and mode of smelter operations were neglected. Acknowledgment is not given in the discussion and summary that the critical concentrations relating to health effects are nothing more than estimated concentrations.

It is questionable whether or not long-term exposures should have been attempted for Magna, based on only one year's record of observations that are abnormal because of the smelter strike. It would certainly have been appropriate to have mentioned that only estimated long-term data were available and indicated their degree of uncertainty in the discussion and summary.

Further, we find many errors on Page 2–37, Table 2.1.A.14. It seems that this table should have never been included in the report. Aside from the misuse of the diffusion model (discussed in Chapter IV) this table lists suspended sulfate values for Magna for the years 1940–1970, that are not the same as listed in Table 2.1.A.16, on page 2–39. The values are estimated by a simple ratio from the smelter emission rates, but this is not explained. On page 2–39 a regression equation is used for the same purpose. All of the sulfate concentrations under the heading CHESS are estimated observations except those for the year 1971. This has not been properly indicated, e.g. by the use of parentheses.

On pages 2–37 emission rates are not sulfur dioxide rates as indicated but emission rates in tons of sulfur per day. This means that the sulfur dioxide emissions were twice the values listed. It also means that the dispersion model estimates are incorrect. However, the listed estimated concentrations in Magna and Kearns, which are based on a simple ratio between observed concentrations in 1971 and some emission rate for 1971, whatever it might be, are not changed.

Note that the regression equation for suspended sulfates, Salt Lake City, (pages 2–39) which is:

$$SS=0.101(TSP)-3.65$$

is quite different than that which can be obtained from Table 2.1.4, i.e.:

$$SS=0.065(TSP)+1.93$$

SO_2 exposures were derived by multiplying the yearly smelter emission of SO_2 by the ratio of the 1971 measured annual average SO_2 concentration to the 1971 SO_2 emission rate (193 tons/day).

Estimates of suspended sulfates were derived from the estimates of SO_2, using the following regression equation for 1971:

$$SS=0.09(SO_2)+6.66$$

The annual TSP exposures were derived by multiplying the yearly smelter production of copper by the ratio of the 1971 measured annual arithmetic mean TSP concentration to the 1971 copper production rate (260,000 tons/year).

Smelter emissions of sulfur dioxide in the early 1940's were roughly three times greater than they were after 1956 although copper production has remained more or less constant. The method for estimating suspended sulfate, which is based on sulfur dioxide estimates leads to very high values in the 1940's whereas the total suspended particulate are estimated lower in 1940 than in 1971. The procedure used produced very high ratios between SS and TSP for the earlier years. For example, the 1940 ratio (34.6/63) is 0.55. This ratio is so large that it is obviously questionable.

The audacity of the estimates can be seen in Figure 2.1.17. The lowest value, which occured in 1971, is extrapolated all the way back to 1940, reaching unusually high annual average concentrations of more than one part per million. Considering the effects of wind direction, which would result in low concentrations much of the time because the smelter stack plume would not be blowing toward the town, such an annual average would result in short-period concentrations many times the annual average. It is questionable that such high concentrations ever occurred. If they did, they would be well-remembered, and living conditions in Magna would be different than in 1971. Such unreasonably high estimates should have been further investigated before being presented.

The grossness of the estimates made overrides other shortcomings in this study pertaining to exposure that might be mentioned. However, more carefully made estimates would have required considerably more work, including obtaining meteorological records and details of smelter operations affecting plume behavior over the period of years studied. Such a large effort may not have been worthwhile considering the inexactness of some of the other aspects of the study. Nevertheless, a study of this nature seems to call for actual observations, more accurate estimates, or considerably less exactitude in its conclusions.

2. Frequency of Acute Lower Respiratory Disease in Children: Retrospective Survey of Salt Lake Basin Communities, 1967–1970

The same comments apply to this study as for the preceding study on the prevalence of disease symptoms in adults. Inadequate recognition is given to the fact that only estimated concentration data are being used in the discussion and summary.

3. Aggravation of Asthma by Air Pollutants: 1971 Salt Lake Basin Studies

In this study, daily entries in a dairy were used to determine weekly asthma attack rates. A statistical relationship was then determined between the attack rates (weekly) and observed air pollution concentrations (averaged weekly). Participants lived within a 2-mile radius of air monitoring stations.

Daily exposure of asthmatics in a community such as Magna, which is close to the smelter, are poorly characterized by a single monitoring station. On a given day, one side of the community could be much more affected by the smelter stack plume than the other, and high concentrations from looping or fumigation might affect one neighborhood but not others. The study inadequately assesses the effects of peak exposures and episodes.

This report does not make clear that the minimum temperatures used were from the Salt Lake City airport. The assumption seems to have been made that temperature was uniform over the entire study area. This is not true because of the differences in elevation and the effects of the mountains, and the lake. Perhaps the differences were not important, but they should have been considered. It is not clear why days were stratified by minimum rather than mean temperature.

Minimum temperatures occur during the early morning when people are generally indoors and perhaps in bed. When temperatures are low, windows are generally closed. Also, lower minimum temperatures are correlated with other meteorological phenomena that could also affect asthma attack rates, e.g., lower humidity and lower wind speed. Further there may be a correlation with wind direction. A lower than average minimum temperature probably is also associated with a strong temperature inversion which would be conducive to lofting the smelter stack plume. Because of the many questions raised, the findings pertaining to temperature merely suggest further study and have no general application.

Near the middle of the left hand column, page 2–89, the following sentence appears. "The shut-down of operations by the strike was accompanied by a pronounced improvement in air quality and a reduction in asthma attack rates that occurred sooner and were larger than seasonal reductions observed in the more distant study communities some 2 weeks later." Here there is a lack of appreciation of the natural climatic differences that exit in the Salt Lake Basin. Some effects of summer weather could easily be delayed two weeks before reaching Ogden. The average date for the last killing frost in Ogden is about May 6, whereas the average date of the last killing frost at Saltair (the climatic station nearest to Magna with a long record) is about April 12.

On Page 2–76 (near middle of page, right hand column) the smelter is not "5 miles north of Magna."

On page 2–81 the first graph in Figure 2.4.1 is incorrectly drafted. After the 17th week the broken line should be solid and the solid line broken. The temperature curve should appear as in the graph for the high exposure community.

Figure 2.4.2, page 2–81, shows a weakness in the argument that the sulfur dioxide concentrations are responsible for the asthma attack rate. In the High Exposure Community the attack rate starts up at the 18th week as the sulfur dioxide concentrations approach zero, or near zero, and remain very low for about six weeks. It is noted that this same graph shows the highest SO_2 peak occurring at the 9th week, which seems to begin about May 9. The graph on page 2–16 seems to show the peak in April.

In Figure 2.4.4, page 2–82, with respect to the High Exposure Community, it may be noted that the sulfate concentrations are not particularly well-correlated with the sulfur dioxide concentrations plotted in Figure 2.4.2, on the preceding page. The highest sulfate reading occurs in the 3rd week, whereas the sulfur dioxide levels build up to a peak in the 9th week.

On page 2–87, left hand column, it is stated that a threshold concentration of 1.4 $\mu g/m^3$ was calculated for suspended sulfates for the higher temperature range. In Figure 2.4.4 all of the plotted concentrations are greater than this value. Considering the background of suspended sulfates generally observed, this low threshold value seems to have no practical significance.

The third paragraph that appears in the right hand column, page 2–89, probably applies to Magna, however, this is not made clear. There is a possibility that the paragraph could be given broader interpretation than actually intended since the last three sentences seem to refer to conditions in urban areas generally. The paragraph probably should have been divided into two separate paragraphs. However, the main fault with the paragraph is that important conclusions are drawn that are not supported by information presented elsewhere in the report. It says "excess asthma attributable to sulfur dioxide might be expected 5 to 10 percent of summer days", "total suspended particulates could occur on up to 5 percent of summer days and 30 percent of fall and winter days", and "excesses due to suspended sulfates are likely to occur on 10 percent of fall and winter days and 90 percent of summer days." Assuming that the stated relationships between concentrations and temperature are true, the report does not explain how the percentages of days were obtained. The study covered only 26 weeks, but these conclusions apply to an entire year. The percentages given seem to be rough estimates since they appear to be given only to the nearest 5 or 10 percent. The percentages might have been obtained from daily values for the minimum temperature, pollutant concentrations and asthma attack rate; but it is not clear how they were obtained.

Presumably daily average concentration levels of specific pollutants were used in the construction of the "hockey stick" curves shown on pages 2–86 and 2–88. The discussion implies that "24-hour levels" were used, but the precise nature of the air quality data used in the threshold analyses is not made clear.

There could be various reasons not explored by the study why the thresholds for asthma attacks were lower on warmer days. One of these is that there may be more plume looping on warmer days. This might result in localized, short-period, high concentrations, but relatively low average concentrations.

The validity of scientific work can be tested by the repeatability of results. In this and the other CHESS studies there were factors affecting asthma attack rates that were not considered and whose effects are unknown. Such factors are: time spent outdoors, percentage of time windows are open, temperature change, relative humidity, etc. The incompleteness of the study and the lack of understanding of the causes of the asthma attacks suggest that it might be repeated with significantly different results.

Short-term exposures to concentrations much higher than average annual or weekly concentrations could have occurred in the communities studied that were near large sources of air pollution such as smelters. There exists the possibility that asthma attacks could be triggered by brief-duration high concentrations. Such exposures could have been determined only inadequately by the procedures used in the study. The report does not make clear why more attention was not devoted to peak concentrations.

4. *Human Exposure to Air Pollutants in Five Rocky Mountain Communities, 1940–1970*

On pages 3–7 through 3–12 beginning with the second column, paragraph near middle of page, which begins "By comparing . . .". There is not a simple relationship between average daily pollutant emissions and average annual pollutant concentrations because the receptor area is often now downwind. Also, some consideration should have been given to determining if the years for which data are available were representative meteorologically.

(Page 3–11) Second paragraph, left hand side of page. Information obtained during this investigation indicates that the ratio 1.63 ± 0.21 should be 1.42 ± 0.21. (The value 1.63 is the upper limit of this ratio.)

(Page 3–12) Emission ratios of particulate and sulfur dioxide for 1971 are omitted from this report. Therefore, it is not possible to verify the ratios given here.

(Page 3–12) According to information obtained during this investigation, the two values for TSP listed as 99.5 for the years 1971–70, should be 98.1 for both years.

5. *Prevalence of Chronic Respiratory Disease Symptoms in Adults: 1970 Survey of Five Rocky Mountain Communities*

Four communities were studied: Bozeman, Helena (Low), Helena (High), Anaconda, and Kellogg. These communities are all in mountainous areas and subject to terrain effects, some much more than others. Average pollution patterns are irregular so that exposures in a particular community will vary considerably. It is particularly important whether the community is somewhere downwind of a source, such as Magna, or on either side of it, as might be the case in Helena (High), or perhaps Kellogg. In these communities assumptions should not have been made about exposure without some effort of sampling and/or meteorological modeling to determine what the actual exposure might be.

In this study long-period concentrations of sulfur dioxide and suspended sulfates are estimated. Also, the most important finding, which was that excess bronchitis occurred with 2–3 year exposure to sulfur dioxide concentrations of 177 to 374 $\mu g/m^3$ and suspended sulfate concentrations of 7.2 to 19.9 $\mu g/m^3$ (in the presence of low total suspended particulates), covers such a wide range of concentrations it has hardly any practical significance.

On page 3–31, in the Summary is stated "Metallic sulfates may well have accounted for the findings of excess bronchitis." The nature of the sulfates is nowhere mentioned in the report. The smelter is apparently the source of only some of the sulfates, and the nature of none of the sulfates has been determined.

6. *Frequency of Acute Lower Respiratory Disease in Children: Retrospective Survey of Five Rocky Mountain Communities, 1967–1970*

Sulfur dioxide levels are crudely estimated from sulfation plate (or candle) data and smelter emission rates. Suspended sulfates are estimated from suspended particulate data using a ratio found in East Helena, Helena and Magna. It was assumed that the estimated values prevailed throughout the community. This is unlikely to have been true considering the topographic effects in the Rocky Mountain Communities. A major shortcoming in this paper is a failure to make clear the inaccuracies that might be associated with estimating the pollution levels.

There is an irregular distribution of annual average sulfur dioxide concentrations in the vicinity of a smelter. These differences affect concentrations in East Helena and can be confirmed by examination of a report on the Helena Valley Environmental Pollution Study.[1]

During 1965–66, 66 measurements of suspended sulfate indicated an average concentration of 7.9 $\mu g/m^3$. The observed total suspended particulate during this period of time was 96 $\mu g/m^3$. Hence the ratio of suspended sulfate observed to particulate during this period was .082. A series of 25 measurements made during the time period April to August 1968 indicated a suspended sulfate to total suspended particulate ratio of 0.057.

Then to determine a ratio range, measurements made during the period June through October at two stations of the Helena Valley study were used. The original information is as follows:

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[1] Helena Valley, Montana, Area Environmental Pollution Study, Environmental Protection Agency Office of Air Programs, Research Triangle Park, North Carolina, January 1972.

Station	Location from stack		Suspended particulate ($\mu g/m^3$)	Suspended sulfate ($\mu g/m^3$)	Ratio
	Deg.	Miles			
1	34	0.8	108	3.5	0.032
3	112	.4	59	4.1	.069

The difference between these ratios is .037, as stated. Station One was the only station in the Study actually located in the town of East Helena.

These observations were made during the warmer months of the year when there would be generally be no frozen ground or snow cover possibly affecting the suspended particulate concentrations. It is not stated when the other observations used in the CHESS study were taken. However, from all of these data came the ratio of suspended sulfate to suspended particulate that was used for East Helena, which was 0.063 plus or minus 0.022.

The ratio of suspended sulfate to suspended particulate determined for Anaconda, which was 0.111 plus or minus 0.057, was determined by taking an average of the East Helena ratio (0.063 plus or minus 0.022) and the Magna ratio of 0.159 (Page 3–11). It is not made clear why this particular ratio was chosen.[3] From Table 2.1.2 a ratio of 0.178 might also have been determined, using a suspended sulfate concentration of 9.6 $\mu g/m^3$ and a suspended particulate concentration of 53.9 $\mu g/m^3$. It may also be noted that the ratio for Magna is much larger than for other locations. No explanation is given for including the Magna value in the average. From the applications of these ratios to estimates of suspended particulate concentrations came the conclusions pertaining to the health effects of sulfates. It is stated that "we conclude that excessive acute lower respiratory illnesses can be expected among asthmatic and nonasthmatic children who are exposed for longer than 2 years to elevated annual average sulfur dioxide levels (177 $\mu g/m^3$) accompanied by elevated annual average suspensed sulfate levels (7.2 $\mu g/m^3$) in the presence of low levels of suspended particulates (65 $\mu g/m^3$)." This statement refers to findings in Anaconda. No mention is made that concentrations of suspended sulfate might range from 3.51 $\mu g/m^3$ to 10.92 $\mu g/m^3$ because of the uncertain nature of the ratio alone.

The following statement from the Helena Valley Study (Page 45) is of interest. "These results (i.e., average concentrations ranging from 2.9 to 4.5 $\mu g/m^3$ for the period of the study) are considerably below the national average and serve to point out that there is no problem from sulfates. It should be noted that the sulfate content is evenly distributed among the five sampling stations, which indicates that there is no significant increase in concentration in the vicinity of the East Helena industry."

Suspended sulfate observations made by the Montana State Department of Health and Environmental Sciences suggest that average annual concentrations of 4 or 5 $\mu g/m^3$ occur in Anaconda [See discussion of Estimate Suspended Sulfate Concentration, 7.2 $\mu g/m^3$ (Anaconda), Chapter II]. Assuming that suspended sulfate concentrations of about 7 $\mu g/m^3$ did occur in the Rocky Mountain communities where certain health effects were observed, the source of the suspended sulfate is inadequately determined. The study findings are much too incomplete to call for the stringent control of suspended sulfates as has been done on page 3–51.

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[3] Referenced publication contains no information pertaining to Magna.

7. *Prevalence of Chronic Respiratory Disease Symptoms in Military Recruits: Chicago Induction Center* (*Paragraph 4.2*)

Exposure estimates in this study are extremely crude. In the summary the following statement is made, "Available evidence indicates that exposures lasting 12 years or more to ambient air pollution characterized by elevated annual average levels of sulfur dioxide (96 to 217 $\mu g/m^3$), suspended particulates (103 to 155 $\mu g/m^3$) and suspended sulfates (14 $\mu g/m^3$) were accompanied by significant increases in the frequency of chronic respiratory disease symptoms."

The 96 $\mu g/m^3$ value is the average urban core value for 1969–70, which ranges from 54 to 138 $\mu g/m^3$, whereas the 217 $\mu g/m^3$ is an average value for five suburban communities for the year 1969. Going back 12 years concentrations were much higher. During the period 1960 through 1965, the lowest value was 222, and there was a high of 344 in 1964. For the five suburban communities there was data only for one other year. It averaged 183 $\mu g/m^3$. The 14 $\mu g/m^3$ concentration for sulfates is for a period of 7 years, not 12 as stated. It basically represents data for the Chicago core area, with some scattered observations from East Chicago and Hammond, Ind. The average concentrations for the city should be somewhat less than in the core area. Use of the core area value would generally result in an overestimate.

It is difficult to characterize exposures lasting 12 years for the entire Chicago area. Either this should have been done in very general terms, nonquantitatively, or a greater effort should have been made to present more representative estimates.

The assumption is being made that sulfate observations made at a central urban location in Chicago, averaged with a few observations from East Chicago and Hammond, Ind. are generally representative of the entire Chicago area.

(Page 4–8) Referring to the Chicago area the following statement is made: "Each sampler location, identified by a station name in Figure 4.1.2, represents the central business-commercial district of that particular area." This statement is not true. Practically all, if not all the samplers are located on the roofs of school buildings in an effort to obtain representative community values. They were not located deliberately in business commercial districts and do not slightly overestimate area-wide concentrations as suggested.

(Page 4–23) In reading this paper about the prevalence of chronic respiratory disease symptoms in military recruits, questions arise about the actual locations from which the men came and the local pollution levels to which they might have been exposed. Some rural occupations result in high exposures to dusts, plant allergens, etc.

(Page 4–35) (Summary) The 12-year value for suspended sulfates should be 16 micrograms per cubic meter, not 14, as stated. Also, it appears that the concentrations of sulfur dioxide and suspended particulate are for only the period 1969–1970 and not for 12 years as is stated. (See Table 4.1.A.6)

8. Prospective Surveys of Acute Respiratory Disease in Volunteer Families: Chicago Nursery School Study, 1969–1970

On page 4–41, in Table 4.3.1, it is not clear where the sulfur dioxide data for the years 1959–63 come from. The Chicago network, which would have provided community data, was not operating effectively until 1964.

On the same page the suspended sulfate data are probably representative for the core area but are high to be used as an average for the city as a whole.

A serious weakness in this study is that the communities are ranked Intermediate, High, and Highest according to a ranking that was determined by suspended particulate values, whereas the most important finding pertains to sulfur dioxide. Referring back to Table 4.1.A.1, it can be seen that a considerably different ranking would have resulted if the communities had been ranked according to sulfur dioxide concentrations. In Table 4.3.1, it may be noted that during the study that the "High" community had the lowest concentration of sulfur dioxide.

Also note in Table 4.1.A.1 that the Highest communities include GSA, which happens to be on the south edge of the Chicago Loop area. This station probably contributed considerably to the high concentration of sulfur dioxide attributed to the Highest community during 1969–1970, yet it is very nonrepresentative of a nursery school. Also, note that the Highest stations include Carver, which for some reason ranks highest because of suspended particulate concentrations whereas the sulfur dioxide concentrations are relatively low.

Sulfates are not considered in the summary of this study, which seems to focus on sulfur dioxide without quantitative considerations of suspended sulfate levels.

(Page 4–54) In the first paragraph of the Summary, the following statement appears: "It is also possible that more recent lower air pollution levels contributed to increased respiratory illness." On page 4–51 the following statement is found. "Acute respiratory morbidity was significantly lower among families living in neighborhoods where sulfur dioxide levels had been substantially decreased." These two statements are contradictory and require clarification. The first statement is remarkable. It can be interpreted to mean that some air pollution is good for you. Did the authors intend to say this? Such an important finding is inadequately supported by the contents of the report.

9. Human Exposure to Air Pollution in Selected New York Metropolitan Communities, 1944–1971

An overusage of estimated data can be found on page 5–19. The following two statements appear: (Left hand column, middle paragraph) "Measured values for suspended sulfates for 1956–1970 were available from the Manhattan 121st Street Station, and these values were used for citywide values." (Last paragraph on page) "The observed annual ratios of suspended sulfate to dustfall for New York City were used to estimate the suspended sulfate levels in Queens and Bronx."

10. Prevalence of Chronic Respiratory Disease Symptoms in Adults: 1970 Survey of New York Communities

Three communities were compared: Riverhead, Long Island, a low exposure community, Queens, an intermediate exposure community, and the Bronx, a high exposure community. Parents of all children attending certain elementary schools located within 1.5 miles of an air monitoring station in each community were asked to participate in the study. Each child was given a questionnaire to be filled out by his parents and returned.

Regarding exposure, were the concentrations measured at the monitoring stations generally representative? Assuming a person remains reasonably near the station, in this case within 1½ miles, and breathes the outside air, the station measurements would be generally representative for long-term average exposure. Maps of annual concentrations which are for sulfur dioxide and suspended particulate matter, show reasonably uniform concentrations across the study areas. However, as has been mentioned in the report (5.1) Human Exposure to Air Pollution Selected New York Metropolitan Communities, 1944–1971, by Thomas D. English, et al., the Queens Community lies about 1 mile west of the John F. Kennedy International Airport. The effect of this airport and the various other possible sources of air pollution that could have affected particular local areas were not determined.

The fact that the CHESS monitoring sites were the same as used in the city air pollution control programs suggests that the sites were picked and are being used because they seem to be generally representative.

More important than the representativeness of the monitoring site locations in this study is the proper interpretation of the effects of the greatly reduced pollution levels during the period 1969–1971. It is not meaningful to draw conclusions from sulfur dioxide exposures ranging from 144 to 404 $\mu g/m^3$ and sulfate exposures ranging from 9–24 $\mu g/m^3$, as was done in this study. The implication is that health effects can be caused by the lowest concentrations mentioned, and this is not shown in the study. Also, it is stated that annual sulfur dioxide levels of 50 to 60 $\mu g/m^3$ (accompanied by annual average suspended sulfate levels of about 14 $\mu g/m^3$ and annual arithmetic mean total suspended particulate levels of about 60 to 105 $\mu g/m^3$) could be associated with such effects. These are levels that were measured in 1971, whereas in the study there seems to have been no way to have differentiated between the effects of pollution in 1971, or that might have occurred during some earlier time. It is not reasonable to infer that lower pollution levels are responsible for the observed health effects.

11. Prospective Surveys of Acute Respiratory Disease in Volunteer Families: 1970–1971 New York Studies

In this study families were telephoned once every two weeks and questioned about possible health effects. The families resided within 1 to 1.5 miles of the air monitoring stations.

In the discussion it is stated that acute lower respiratory disease morbidity can be attributed to exposures to 2 to 3 years involving annual average sulfur dioxide levels of 256 to 321 $\mu g/m^3$ (accompanied by elevated annual average levels of total suspended particulate of

97 to 123 $\mu g/m^3$ and annual average suspended sulfate levels of 10 to 15 $\mu g/m^3$). These values are average values for the period 1966–1970, a five year period, and not period of 2 to 3 years as indicated. Also, they are the averages for the Bronx and Queens, respectively, and therefore do not represent a range of concentrations that would have occurred in any particular community, as implied. For example, the sulfur dioxide concentrations in the Bronx ranged from 184 to 472 $\mu g/m^3$ and in the Queens from 131 to 420 $\mu g/m^3$, during the five year period. Three year averages are 174 to 247 $\mu g/m^3$, and two year averages, lower still.

On page 5–16 the dustfall concentrations shown in Figure 5.1.21 seem to be greater than would be obtained from the data presented in Figure 5.1.16.

On page 5–36 (Table 5.2.1) the values in this table seem to come from Table 5.1.A.8. The values in the column headed 1949–58 are, except for dustfall, for shorter time periods. For example, the values for Queens come from data for the years 1956–58.

On page 5–45 (Summary) we find that since the concentration data base comes from Table 5.1.A.8, the long term exposure values represent a period of less than 20 years.

Further, it is stated that there is a distinct possibility that increased susceptibility to acute lower respiratory illness is maintained or induced by exposures involving annual average sulfur dioxide levels of 51 to 63 $\mu g/m^3$ (accompanied by annual average total suspended particulate levels of 63 to 104 $\mu g/m^3$ and annual average suspended sulfate levels of 13 to 14 $\mu g/m^3$). The 51 to 63 $\mu g/m^3$, is a range resulting from two different analyses of samples (see page 5–53). It represents uncertainty in measurement techniques rather than a range of exposure as would be interpreted. These concentrations and the suspended sulfate concentrations of 13 to 14 $\mu g/m^3$ happen to have occurred in the Intermediate I and the Intermediate II communities during 1971. This particular study as conducted could not have differentiated between the effects of these levels of pollution and the effects of higher levels that occurred earlier.

Only average annual concentrations were considered and not peak or episode concentrations.

12. Aggravation of Asthma by Air Pollutants: 1970–1971 New York Studies

Panelists who lived within a 1.5 mile radius of three monitoring stations in communities identified as Low, Intermediate I, and Intermediate II, because of their average air pollution concentrations, recorded asthma attacks each day in a diary for a period lasting 32 weeks, October 1970–May 1971. From a statistical association between asthma attack rates, 24-hour average concentrations from the monitoring stations, and daily minimum temperatures from airports near the study communities, it was concluded that 24-hour suspended sulfate levels of 12 $\mu g/m^3$ on cooler days (T_{min} equal to 30 to 50°) and 7.3 $\mu g/m^3$ on warmer days (T_{min} greater than 50°F) were thresholds for the induction of excessive asthma attacks. No firm evidence could be found to associate elevations in sulfur dioxide (100 to 180 $\mu g/m^3$ on 10 percent of days) with excessive asthma attack rates on either cold or warmer days.

Regarding exposure levels, there is much less assurance that daily average levels throughout a community would be more or less uniform than would be the case with annual average levels. More monitoring stations might have been operated, or mobile stations used, to determine how pollution exposure varied from location to location. The determination of such differences in air pollution concentrations might have been important, but probably more important is that the other factors (in addition to the observed air pollutants) that could have caused or contributed to the asthma attacks were not examined. It would not be worthwhile to refine the information on the distribution of the air pollutants studied, unless a greater effort were made to study all of the various possible causes of the asthma attacks more thoroughly.

The study focused on the effects of minimum temperature. The possible effects of other meteorological variables could also have been explored. Of particular interest would be the effects of sudden, large temperature changes.

It is not made clear why minimum instead of average, or even maximum, temperatures were picked for correlation. Generally there would be less actual exposure to minimum temperature, which usually occurs about sunrise, than to warmer temperatures. Asthmatics would generally be expected to protect themselves from colder temperatures, staying indoors and keeping windows closed, whereas on warmer days they might be more subject to exposure to outdoor air with its assortment of possible allergens. There are diverse reasons why temperature might be an important factor determining asthma attack rates. No attempt was made in the study to provide an explanation.

It is expected that there would be noticeable temperature differences between Riverhead (the Low community) and Queens (the Intermediate I, community). Although it is stated that the temperatures come from nearby airports, the temperature curves plotted in Figure 5.4.1 seem to be identical for both communities. It may be noted that a different curve is plotted for the low community Figure 5.5.2.

(Figure 5.4.4) Although at a glance it appears that for the Intermediate community that the "Attack Rate" and the "Suspended Sulfate" curves are similar, close inspection shows that more often than not, they are out of phase. Between the 2nd and 3rd week the attack rate (AR) curve continues down as the suspended sulfate (SS) curve starts up, between the 10th and 11th week the AR-curve continues down after the SS-curve starts up, between the 14th and 16th week the AR-curve goes up while the SS-curve continues down, between the 19th and 20th week the AR-curve starts up while the SS-curve continues down, and again on the 27th week the AR-curve rises a week before an increase in the suspended sulfate concentrations. In all, three of the five increases in attack rate precede, rather than follow, increases in suspended sulfate concentrations.

13. Frequency and Severity of Cardiopulmonary Symptoms in Adult Panels. 1970–1971 New York Studies (Paragraph 5.5).

Symptom diaries were maintained daily for the 32-week period October 8, 1970 through May 22, 1971, by four panels, depending on state of health. The panelists were distributed in three communities and lived within 1.5 miles of air pollution monitoring stations. It was concluded that elderly panelists in the low exposure community reported higher symptom rates on days when sulfate levels exceeded 10 μg/m³. There seemed to be good evidence of a threshold effect between 6 and 10 μg/m³, with a greater morbidity excess on warmer days.

Since suspended sulfates seem to be more uniformly distributed than a pollutant such as sulfur dioxide, the concentrations determined by monitoring should be generally representative of outdoor exposure and in most cases indoor and outdoor average exposures would be expected to be similar. The question not answered by this study is whether or not the panelists are also being exposed to some other causative agent, or stress factor, that might happen to correlate with the sulfate concentrations. It, and not the suspended sulfate concentrations, might be the cause of the observed health effects.

(Page 5–91) (Figure 5.5.3) The low value of sulfur dioxide that began at the 19th week and continued until the 24th week are suspected of not being true values. Near the end of the last paragraph on the preceding page it is suggested that meteorological conditions may have been responsible. A careful study of the meteorological conditions and fuel usage would be necessary to determine if these might have caused the persistent low concentrations. However, a scanning of the daily local climatological data shows no obvious reason for the reported low values.

Furthermore, the minimum temperature curve for the Low community in Figure 5.5.2 is not the same as given in Figure 5.4.1.

The New York Department of Air Resources also reported a large drop in concentrations following the mid-winter peak at the Queens (Intermediate I) monitoring station, but reported values were never as low, and a period of low values was not followed by a rise as shown in the Figure. Further, the low values shown, which are about 25 μg/m³, or .01 ppm or less, are quite low for the New York metropolitan area. Average weekly low values two or three times this value would generally be expected for a comparable period.

14. Ventilatory Function in School Children: 1970–1971 New York Studies (Paragraph 5.6).

Pulmonary tests were made in three elementary schools in communities with different air pollution levels, and there were four rounds of testing, November-December 1970, January 1971, February-March 1971, and April 1971. The children lived within 1.5 miles of a particular air monitoring station. The Queens monitoring station is on top of a school where the testing was done. However, the Bronx station is on top of a "court house in the center of a busy commercial area" (page 5–6) and may not be close to the school. For the Riverhead community it is not made clear whether or not the school and the monitoring station are at the same location or near each other. It is assumed that the schools in Riverhead and the Bronx were within 1½ miles of the monitoring stations, but this is not actually stated.

It was concluded that 9 or more years exposure to annual sulfur dioxide levels of an estimated concentration of 131 to 435 μg/m³ (accompanied by suspended particulate levels of about 75 to 200 μg/m³) and suspended sulfate levels of about 5 to 25 μg/m³ can be associated with a small but significant impairment in ventilatory function. These values are from Table 5.6.2, and are the extreme high and low values listed. There is an implication here that the low concentrations, 131 μg/m³ for sulfur dioxide and 5 μg/m³ for suspended sulfates represent threshold values. Actually they are only annual average concentrations for the years 1969 and 1970. The observed health effects may have been the result of exposure to much higher concentrations in other years, or to some other cause.

15. Ventilatory Function in School Children: 1967–68 Testing in Cincinnati Neighborhoods (Paragraph 6.1).

This study included a pair of public elementary schools in each of six neighborhoods differing in socioeconomic level, race, or pollution exposure. All children in one or two classrooms of the second grade of the elementary schools were asked to participate in the study to achieve sample sizes of 60 to 75 children in each of the six study sectors. Ventilatory performance as measured by a spirometer was obtained 12 times from each child: once weekly in the months of November 1967 and February and May 1968. The tests were administered on Tuesday and Wednesday mornings.

Air monitoring stations were placed in locations within three blocks of each school to provide samples representative of the air quality in the neighborhood served by the school. No information is reported on the distances of the homes of the children from the school. Apparently it was assumed that the home environment and the school environment were the same. Indoor soiling index and sulfur dioxide observations were taken in the schools, but results are not reported. It is reported that it was determined that indoor and outdoor sulfur dioxide, soiling index, and suspended particulate levels measured over the 24-hour or 4-hour period directly preceding pulmonary function tests did not consistently correlate with the test values.

Details of this lack of correlation are not given, but it was concluded that "ventilatory performance of children thus did not appear to be acutely affected by variations in pollutant levels on the day of the test." Possible exposures over intermediate periods, say three days or one week, prior to testing were not considered. Conclusions seem to be based on possible long-period exposures, probably over a lifetime.

Concentrations of sulfur dioxide were low (less than 52 μg/m³) in all areas, so health effects were attributed to particulate pollutants independent of atmospheric levels of gaseous sulfur dioxide.

Average sulfate levels during the period of the study were observed to be between 8.9 and 10.1 μg/m³, in the polluted lower middle white community, but previous average exposure was estimated to be 10.7 to 12.1 μg/m³, based on the National Air Surveillance Network station. The average suspended sulfate level in the clean white sectors was 8.3 μg/m³, a relative difference of 13 percent. (The largest differences in area exposure were in the concentrations of suspended particulates. Levels of total suspended particulates were 131 μg/m³ in polluted sectors and 61 to 92 μg/m³ in clean sectors.

In reading this paper one wonders about the psychological interaction between the children and the team members administering the tests, who could anticipate the outcome of the experiment. The curves for the black children in Figure 6.1.3, are particularly interesting.

There was only 0.1 μg/m³ difference between the average sulfate levels between the Clean Lower Middle Black and the Polluted Lower Middle Black, yet there was a large difference in ventilatory function that disappeared as the study progressed. The discussion acknowledges a culturally determined response of these children to the white interviewers. The effect of the interviewers on all of the children may have been greater than was realized.

It was concluded that the observed area effect on ventilatory performance was probably attributable mostly to suspended sulfates. There is no particular reason to challenge the estimated average exposure of the children to suspended sulfate concentrations. However, it should be noted that the sulfate level in the "clean" school #4, was 9.1 μg/m³, more than the 8.9 μg/m³ concentration in the polluted schools #8, #11, and #12. The sulfate concentration differences between the schools is acually very slight. It seems far-fetched that the observed average differences in ventilatory performances were caused by a difference in suspended sulfate concentrations of only 1.2 μg/m³.

C. SUPERFICIAL AND PERFUNCTORY TREATMENT OF METEOROLOGICAL INFORMATION

A discussion of meteorology is included in the CHESS report on the studies in the Salt Lake Basin, Chicago, and New York. The treatment is so superficial and perfunctory that there is hardly any usefulness. Little attempt has been made to tie the meteorological information with information subsequently presented, or to use it to make clearer the possible reasons for the study findings.

The air flow over the Salt Lake Basin is much more complicated than implied by the wind information included on pages 2–4 and 2–5. Winds in the vicinity of the Oquirrh Mountains, where the smelter is located are significantly different from those at the Salt Lake City airport. Also, the wind rose for Hill Air Force Base shows the effect of a nearby canyon and is not indicative of air trajectories affecting the Ogden area generally. The meteorological discussion on these pages could have made clearer the fact that Ogden is rarely, if ever, affected directly by the smelter plume, and that Salt Lake City is infrequently affected.

Similarly, Chicago winds are inadequately explained by the Midway and O'Hare Airport wind rose; and the reader remains unsure of the wind conditions at Riverhead even though John F. Kennedy and La Guardia wind roses are given.

Even so, the wind rose data, no matter how carefully given, is of practically no value for interpreting the CHESS studies because source-receptor orientations are generally unknown and were not a factor considered in developing the CHESS conclusions.

D. INSUFFICIENT EXPLORATION OF POSSIBLE RELATIONSHIPS BETWEEN METEOROLOGICAL CONDITIONS AND ASTHMA ATTACK RATES

With regard to meteorological correlations, the CHESS studies for the most part only explored a possible relationship between asthma attack rates and minimum temperature. In designing studies of asthma attack rates it would seem that steps would have been taken to investigate other meteorological factors also. Of particular interest would be the effect of large and sudden temperature changes. Some other factors that could affect asthma attack rates are relative humidity, frontal passages with their change of air mass, wind direction and speed, precipitation, type and amount, frozen or wet ground, and possibly atmospheric pressure.

A community study of asthma attack rates would also be expected to take note of any air pollution episodes resulting from atmospheric stagnation that occurred during the course of the study. If there were none, notice would be taken of this also.

E. FAILURE TO CONSIDER PEAK AND EPISODE CONCENTRATIONS

The CHESS studies do not adequately consider the short-period exposures to high concentrations that would occur in the smelter communities. It is conceivable that two different communities might have similar annual average concentrations of sulfur dioxide whereas one of them might be subjected much more to short-period high level concentrations that could trigger health effects, asthma attacks in particular. Three causes of much higher than average concentrations are plume looping, plume fumigation associated with the dissipation of a surface-based temperature inversion, and episode conditions caused by a shallow mixing layer and light winds, perhaps with fog.

In order for the CHESS studies to be complete much more needs to be known about the short-period exposures to high air pollution concentrations in the smelter communities.

F. USE OF A SINGLE MONITORING STATION TO DETERMINE THE EXPOSURE OF A COMMUNITY

Although it may be reasonable to assume an average concentration based on a single monitoring station in a large metropolitan area without any well-defined sources of air pollution, such an assumption may not be reasonable in a mountain community with a single large source such as a smelter and possible topographic effects. For example, air pollution concentrations in East Helena, Anaconda, and Kellogg are likely to be rather non-uniform. There is no assurance that the air quality values being used by CHESS are average, or that some families were not subjected to much higher or lower levels of pollution.

One would expect in community studies such as conducted under CHESS that more effort would be made to determine if a single monitoring station is sufficiently representative, particularly in areas where there is but one major source of air pollution. More use could have been made of meteorological techniques in the CHESS studies to estimate exposures and the representativeness of monitoring stations, including the wider application of simple dispersion models. Where there were particular sources, wind direction frequency information should have been examined. Generally, a visit by a meteorologist to a monitoring station location would have been helpful in determining its suitability. Temporary or mobile monitoring stations might have been used to determine if there were significant concentration differences from one location to another within a community.

G. FAILURE TO ESTABLISH SIMILARITY OF EXPOSURE AND STRESS FACTORS BETWEEN COMMUNITIES IN THE SAME STUDY, EXCLUDING THE EXPOSURE TO SPECIFIC POLLUTANTS

No account seems to have been taken in the CHESS studies of actual exposure inside of buildings with various kinds of ventilating or air conditioning systems, or from air at various elevations above ground. Neither was there any effort to determine if there were any significant differences in vegetation. Any of these things might have caused the actual exposure to air pollutants and allergens to be quite different from that estimated on the basis of usual ambient air monitoring. Further, the general stress factors affecting health are no doubt different in the Bronx than they are in Riverhead, or perhaps between Ogden and Magna, where, for example, homelife might have been upset by the smelter strike.

Still another shortcoming was that no information was collected on possible exposures of individuals when they went outside of the study community.

The CHESS reports do not carefully distinguish between outdoor concentrations such as might be measured at a monitoring station and true exposure, which might be significantly different. Throughout the report the concept of dosage is never used. Whole communities were assumed to have the same exposure and presumably were considered to have received the same dosage. A more careful study might have considered the actual community dosages of air pollutants, which might be significantly different, even though the potential exposures are the same.

H. IMPRECISENESS OF MONITORING STATION LOCATIONS

Monitoring stations used in the CHESS studies are not precisely located within the community with which they are identified. In some instances it may not be necessary to know the exact geographic location, but it is not true for a community such as Anaconda. The Rocky Mountain Studies report leaves completely indefinite where the Anaconda station was located with respect to the smelter, or the community itself. It may even be possible that more than one station is involved in the determination of the exposure estimates. Similarly the reader of this particular report has no idea where the monitoring stations in the two Helena areas were located. Perhaps the general nature of the epidemiological studies is an excuse for omitting details, but a follow-up effort to verify some of the CHESS results would require the precise location of certain monitoring stations from which exposures were determined.

I. INEXACT LOCATIONS OF RESIDENCES OF INDIVIDUALS STUDIED

Assuming that an attempt was made to apply meteorological modeling techniques to better determine exposure in the CHESS studies, there would be a severe limitation on what could be accomplished because the locations of residences of participating individuals within the study area are never given except to say that they are within a certain radius of a monitoring station.

There are two problems. First, one cannot be sure that the population was all within the stated radius as claimed. Inquiries made in New York and elsewhere indicate that some of the children studied rode school buses for greater distances and that for various reasons some other participants in studies lived outside of what might be considered the effective radius of an air monitoring station. Second, and probably much more important, are the uncertainties with respect to populations in the vicinity of single large sources such as the smelters in the Rocky Mountain communities. Insufficient information has been given about the distance and direction that participants lived from the smelter stack, and perhaps where they live with respect to significant topographic features. When determining possible exposure, it is particularly important to know if participants lived in different directions from the stack because of the effects of wind direction.

In general, the conclusions from the CHESS studies are weakened because there is a lack of assurance that the populations were actually located as claimed, and in the smelter communities that the populations were so located with respect to a stack, or stacks, that it is feasible to represent exposure with a single monitoring station per community. The presentation of maps that showed, at least in a general way, the location of the residences of participating individuals would have helped to engender more confidence in the estimated exposures.

These comments, many of which are minor and have various orders of significance in total implication, are an indication of the many observations which cumulatively support the need for careful peer review of each research project. In the limited time available for analysis of historical research of this nature, it is difficult to determine the net impact of these errors on the final conclusions in the study but such errors certainly tend to reduce the credibility of the research results as published.

APPENDIX B

LEGISLATIVE HISTORY OF THE CHESS PROGRAM

The programs now referred to as CHESS studies evolved during a period of increasing concern about air pollution. This same period produced significant changes in government organization to cope with new air quality legislation and substantial increases occurred in the funding levels in support of this legislation. In order to place this evolution in some legislative perspective, the following brief history has been prepared. The information is summarized and citations are primarily (except as noted) from House Appropriations Hearings held during the period 1964–1975.

By 1964, well before the 1974 publication of the 1970–71 CHESS studies, air pollution health effects had been under investigation within the Department of Health, Education and Welfare's (DHEW) Bureau of Disease Prevention and Control, National Center for Air Pollution Control. The Center was conducting clinical and laboratory studies in humans and experimental animals. The plans of the Center included a comprehensive program of research on the health effects of exposure to oxides of sulfur alone and in combination with particulates. In addition to clinical and laboratory studies, epidemiological studies were planned for the St. Louis-Philadelphia areas as well as a continuation of a statewide study in Alabama to assess the relationships of air pollution to the prevalence of pulmonary emphysema. The budget proposals in 1964 were the first to be specifically related to the Clean Air Act which had been adopted in 1963. At that time also, there was a concern within the scientific community about the conversion of SO_2 to sulfate and the potential health effects of such sulfates. (Estimated funding levels for 1965 were $2.1 million for the medical and biological studies and $1.5 million for the epidemiological studies).

In 1965, a spokesman for the Air Pollution Control Center indicated during hearings that the 1963 Clean Air Act had opened "a new era of opportunity to cope with the growing national problem of air pollution. . . . There is overwhelming evidence that air pollution is a serious threat to public health and welfare as well as an economic burden costing the Nation several billion dollars annually." In the request for appropriations at that time, the Center indicated an intent to continue the same programs supported in the previous year. Again, studies of the acute and chronic effects of inhalation of oxides of sulfur were specifically cited as receiving support. Human experiments to study the effects of these pollutants under controlled laboratory conditions which had been accelerated in 1965 were designated for expansion in 1966. Additional surveys to identify field sites with varying levels of sulfur oxides and to clarify the effects on human health of single pollutants or single-source pollutants were identified as priority fields for investigation. A small increase to support these additional studies was requested.

The field studies identified for continuation in the 1967 program included the Alabama air pollution-emphysema studies and the detection of asthma epidemics; the epidemiology of air pollution of asthma in New Orleans, and the relationships between air pollution and absenteeism. It was also indicated that in 1967 there would be a retrospective survey of the effect of air pollution on human health through the use of Social Security disability records, Veterans' Administration records, and insurance records. A study of nursing home residents as a high-risk group was to be initiated and a study to survey air pollution in San Antonio was planned to place special emphasis on the synergistic effect of man-made air pollution and aeroallergens. A mortality study in large cities to determine if excess mortality could be correlated with air pollution was considered for support.

Studies scheduled for continuation in 1968 included the Alabama studies mentioned previously; the New Orleans studies; the continuation of the excess mortality studies; and the designation of Chicago as one area for studying the correlation of disease with air pollution.

Plans for 1969 again emphasized the need for continuation of studies on several air pollutants including sulfur oxides. By this time, the testimony being provided to the Appropriations Committees was citing as justification for some of the work the new requirements specified in the 1967 Air Quality Act. The need for data to develop air quality criteria was being emphasized as a prime goal for the continuation of many of the epidemiological studies. The criteria for sulfur oxides had been published. By July 1, 1968, the reorganization plans of the Administration had resulted in the establishment of the Consumer Protection and Environmental Health Service, and the responsibility for air pollution programs was assigned to the National Air Pollution Control Administration (NAPCA). Objectives of this reorganization included increased autonomy and a higher visibility within DHEW for the air pollution control programs. Progress cited during the 1969 hearings included the publication in the Federal Register of February 11, 1969 of the air quality criteria and related information on control technologies for sulfur oxides and particulate matter. The discussions also directed attention to the increased level of activity required to generate data on health and economic effects of pollutants. Plans for leasing facilities at Research Triangle Park (RTP), North Carolina, for NAPCA were under way and an increase of almost $11 million for this transfer was requested. Among the many justifications offered in support for the concentration of air pollution research at RTP and the move to that location of personnel from DHEW Washington and Cincinnati facilities was the planned construction of the new National Institute of Environmental Health Sciences at RTP. It was believed that a consolidation of NIEHS and NAPCA at RTP would facilitate general planning and centralization of related research programs. A continued expansion of the general air pollution monitoring network was supported.

Hearings in 1970 indicated that further reorganization of the Environmental Health Service had occurred with the splitting out of the Food and Drug Administration. Fiscal Year 1971 was designated as a key year for developing Federal-State machinery for effective national control of air pollution. A majority of NAPCA personnel were located at RTP and close liaison with NIEHS was cited as real and viable. By this time, NAPCA was referring to the epidemiological studies which were being correlated with air monitoring collection as a health surveillance network (HESN). The effort was described as a "medical research effort destined to assess changes in the health of the population as a result of air pollution control program activities. It is also specifically directed toward conducting studies in unique air pollution types so we can have the kind of data we require for the proper development of air quality criteria." A Chattanooga, Tennessee study of nitrogen dioxide emissions was described as a specific example of the type of study intended to provide data for further air quality criteria development. At this time the HESN program was being highlighted among the several types of epidemiological studies and funding levels for FY 1970 were estimated for this program at about $400,000 with an expected growth in 1976 to about $2.3 million. Other epidemiological studies had been initiated or were planned including studies of air pollution in New York and Seattle, and in several university grants. In general, the HESN program involved cities purportedly selected for high to low exposure gradients to specific pollutants to correlate with appropriate health indicators, as a means to measure health effects. The HESN program had as its objective the construction of a framework of information in which selected health parameters such as pulmonary functions, acute respiratory disease and chronic respiratory disease could be evaluated at one or more points in time. The network was to be initiated on a nine-city basis in fiscal year 1970 and was to be expanded to a 12-city basis in fiscal 1971.

By appropriations hearing time in April 1971, a major Executive Reorganization had occurred (Plan No. 3 of 1970—December 2, 1970) and the air pollution program had been transferred from DHEW NAPCA to the newly created Environmental Protection Agency. At this time, Mr. Ruckelshaus, the first Administrator of EPA to appear before an appropriations committee, provided some summary data about the health effects surveillance studies which had now been given the new acronym CHESS (Community Health Effects Surveillance Studies). Despite this change in title, it was obvious that the CHESS studies were simply a further expansion and formalization of the HESN programs which in turn had evolved from earlier effort in epidemiology. Several of the comments offered by Mr. Ruckelshaus are of interest as they relate to the priorities associated with CHESS at that time:

> CHESS studies have already associated environmental pollution with a number of health problems. Air pollution was associated with significant increases in acute respiratory diseases among schoolchildren and their parents who also reported chronic respiratory disease symptoms more frequently. Both parents and children residing in polluted areas exhibited significant decreases in lung function not accounted for by other factors. Asthmatics were also adversely affected, reporting more attacks on days with increased air pollution.
>
> The CHESS concept is anchored to extensive environmental and health monitoring in sets of communities demonstrating an exposure gradient for specified pollutants. Three years of intense effort have been devoted to the design and field testing of the health impact indicators now a part of CHESS. The air quality aspects of CHESS will not be fully operational until 1973 and will evaluate the health effects of specific pollutant sets. In other words, the air quality aspects of

CHESS are designed to obtain the maximum amount of health effects information about the most important air pollutants. These effects will be continually monitored as pollution is controlled and can thus document the health benefits of abatement. Extending intensive CHESS air monitoring with limited health monitoring to a larger number of cities would probably be counterproductive in terms of health information.

In May, 1972, Dr. Stanley M. Greenfield, Assistant Administrator for Research and Monitoring, EPA, listed as the objectives for CHESS:

> First, to evaluate existing environmental pollutant standards as these relate to health. Second, to measure pollutant burdens in exposed populations. And third, to determine the health benefits of environmental pollution control; that is decreased adverse health effects as a result of improved environmental quality.
>
> Presently, major CHESS studies are being conducted in the following areas: New York City; Chattanooga, Tenn.; Birmingham, Ala.; Salt Lake City, Utah; and Los Angeles, Calif.
>
> CHESS operations essentially involve four basic integrated functions; data collection; bioenvironmental measurement; information synthesis; and research and development.

Testimony at the time indicated that about $6.7 million was programed for the CHESS program for fiscal year 1973 with operations anticipated in 27–30 communities in five geographical areas. To add additional areas was estimated to require about $1 million and 15 staff persons per area. CHAMP (Continuous Health Air Monitoring Program) was described for the first time during these appropriation hearings as an integral portion of the CHESS program which would eventually be the total air measurement part of CHESS. As noted by Dr. Greenfield:

> Comprehensive monitoring is required to relate changes in sensitive health indicators to existing environmental pollutant levels. From these data, pollutant effects that occur from very short exposure, that is, from 10-minute peak to 24-hour average values, can be documented and available for ambient air quality standard setting. To date, stations [CHAMP] in the Los Angeles Basin have been selected, partially equipped, and data is being transmitted to North Carolina [RTP]. The cost for initiating the more comprehensive CHAMP program, to have 27–30 completely equipped and installed stations, is $2,400,000. The in-house costs are $750,000 and the contract costs are $1,650,000. The contract includes $465,000 for operating the stations in Los Angeles for this year. The yearly operational costs for the 27 to 30 stations will be $1,240,000; $465,000 is in contract and $775,000 of in-house funds.

During the 1973 hearings, the question was raised as to whether the health effects being measured in the CHESS studies were actually based on medical diagnosis and not on individual reports of health on a questionnaire which "then some research clerk codes as a specific disease." Mr. Ruckelshaus replied:

> To the fullest extent possible, the medical response to EPA health questionnaires are validated by appropriate techniques. It would not be possible to have a physician visit the home of thousands of respondents to ascertain if their responses to medical questions were correct. However, we can assure the committee that the questionnaires we employ are a representative subset of the responses received and have been appropriately validated against physician records. Further, the questionnaires used in the CHESS program were previously well validated with clinical examinations by competent investigators.

In more detailed hearings held in September 1973 (Committee on Interstate and Foreign Commerce) it was already being reported that the CHESS program had provided information that adverse health effects might be more closely associated with suspended sulfates than with SO_2 or total suspended particulates. The time period estimated at that time to permit expansion and modification of health effects research on sulfuric acid and suspended sulfates in the ambient atmosphere was 5–10 years. A very extensive expansion of the study of oxides of sulfur with emphasis on sulphates, including sulfuric acid, was being recommended. The FY 74 program was estimated to be about $1.2 million with about $780,000 devoted specifically to the CHESS studies, the remainder directed toward supportive biomedical research, methods development, atmospheric chemistry and monitoring. Reference was made to the fact that the data from CHESS suggesting significant health effects from sulfates had been presented in a scientific conference as early as December 1972. The total air-health research program was summarized as having expanded from about $4 million in FY 69 to about $11 million in FY 74. During this hearing, EPA personnel pointed out that the National Academy of Sciences was reviewing a number of data bases on air pollution health research and would be providing reports.

At this time, the program at RTP was being affected by management adjustments involving the transfer of temporary personnel to permanent positions with some total reductions in personnel as a result of insufficient permanent positions to accommodate all temporary personnel. Thus, although the air-health effects program at RTP showed some growth in general trends, there actually appeared to be some slowing of growth and some adjustments in programs because of the impact of inflation and fewer permanent positions than had been anticipated. With regard to the National Academy of Sciences' review of the EPA research program on sulfates, it is of interest to note that shortly after these congressional hearings, the implications of the potential dangers of sulfates were discussed and acknowledged by several investigators at an Academy conference. At this same conference, however, Higgins and Ferris noted with regard to the EPA CHESS studies:

> This is not the place to criticize these studies in detail. A few general points only will be made. The need for a great deal of information in the shortest possible time has meant that the E.P.A. has been forced to attempt too much too superficially. A more deliberate approach with outside consultation might have led to a more solid body of knowledge. As it is, the studies have a number of deficiencies which make evaluation difficult. The samples studied, the response rates in certain categories, the methods and procedures which have been used and the analysis of the results can all be criticized. It is particularly disquieting, in view of these deficiencies, that there has been a tendency to select findings which point to an effect of pollution on health and ignore those which do not. Perhaps the wisest conclusion which can be drawn from these studies in relation to current standards is that taken in the aggregate they do not appear to justify any lowering of the current standards for SO_2 and particulates. But on the other hand neither do they suggest that any relaxation of these standards is justified.[1]

It is of interest for purposes of this report that the Academy in the final report to the Senate on the results of a special review of the health effects of air pollutants noted also with regard to the CHESS report:

> The 1970–1971 CHESS studies have received a good deal of criticism, although it must be noted that many of the potential problems are discussed in detail in the CHESS document (EPA 1974). Specific problems with the two asthma studies

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[1] Higgins, Ian T. T. and Benjamin G. Ferris. Epidemiology of Sulphur Oxides and Particles. In: Proceeding of the Conference On Health Effects of Air Pollutants. U.S. Senate. Committee on Public Works. Proceedings of the Conference on Health Effects Of Air Pollutants. 93d Congress, 1st session. November 1973. Serial No. 93-15. Washington, D.C., Govt. Print. Off. p. 247.

> described above include the relatively poor response rate and high turnover, which may be inherent in diary studies of patients with this disorder; the presence of anomalous data, such as a decrease in the temperature-specific risk of asthma attacks associated with increasing sulfate concentrations on days when the minimum temperature was 30–50° F in the Salt Lake area; the failure to consider temperature change, rather than absolute temperatures; the lack of information on atmospheric allergens, which conceivably vary with pollution concentrations; and the tendency toward overanalysis and overinterpretation of the available data. Reasonable preliminary conclusions from these studies are that they do provide support for the association of air pollution with asthma attacks and that they further implicate suspended sulfates as an important deleterious component of polluted air. It does not appear to be necessary or reasonable at this time to draw firm conclusions concerning the 1970–1971 CHESS asthma studies, inasmuch as data have been collected and analyzed for later years and the reports will be forthcoming soon. If the more recent studies are able to replicate the 1970–1971 findings, this will provide much firmer support for the interpretations advanced by the CHESS investigators.[3]

In April, 1974 Mr. Train, now the Administrator of EPA, pointed out that he considered 1975 to be a critical year for the EPA air programs. He emphasized the need for considerable more research in:

> Better defining the health effects of air pollutants, determining the causes and effects of atmospheric concentrations of sulfates and developing improved instrumentation and analytical methods for monitoring air pollutants.
>
> Our proposed 1975 program shows a substantial increase of approximately $9 million over the funding levels of this area during 1975.
>
> The overwhelming bulk of this increase, some $7 million, will be used to considerably accelerate our programs dealing with the health effects of air pollutants.

During detailed hearings in July 1975 held by the Subcommittee on the Environment and the Atmosphere, Committee on Science and Technology, Dr. Greenfield, as a former administrator of EPA research which included the CHESS programs, provided comment on this program from his new perspective as a private consultant:

> If you take the report from CHESS for 1974, the thing that is forgotten is that this relates to the data that was collected in 1970–71. Where are the data for 1971–72 and 1972–73. These have never been released. Yet, if you go back and look at these data there are interesting ambiguities relative to the correlations between sulfates and these health effects and whether or not they show up again the following year. There are interesting ambiguities, for example, in the number of chronic bronchitics shown in the 1970–71 period that actually dropped out in the 1971–72, as if you have suddenly removed chronic bronchitis, and they don't remove from the population in that way, which raises serious questions as to whether or not the sampling techniques were really correct.
>
> Finally, we come to the question of health effects, and potentially dangerous pollutants. I do not want to spend a great deal of time describing the EPA Community Health Environmental Surveillance System, the CHESS program. I'm sure that's been described here previously. But these studies have given rise to the most recent sulfur oxides health effects data which have implicated sulfates. Suffice it to say that this was a massive epidemiological program, probably the largest ever attempted, but suffers from many of the deficiencies inherent in all such studies. These deficiencies identified by the CHESS investigators, themselves, have included an [in] ability to adequately quantify the exposure of individuals to various pollutants simultaneously present. These deficiencies preclude the ability to unilaterally ascribe the observed adverse health effects to any single pollutant. It should be noted that an even more fundamental problem pervades those data that purport to demonstrate adverse health effects due to sulfates. The sulfates measured were total water soluble sulfates. No attempt was made to separate the various sulfate, and sulfite, compounds so as to determine which forms may be innocuous and which forms may be deleterious. Neutral sulfate compounds such as sodium and magnesium sulfate occur naturally.

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[3] U.S. Senate. Committee on Public Works. Air Quality and Stationary Source Emission Control. A Report By the Commission on Natural Resources, National Academy of Sciences, National Academy of Engineering, National Research Council. March 1975. Serial No. 94-4. 94th Congress, 1st session. Washington, D.C., Govt. Print. Off. p. 81.

> Are these compounds harmful? If not, what fraction of the measured sulfates represent a potentially harmful concentration? The problem is further compounded by the fact that nitrates may correlate better with the selected health indicators than sulfates, and this, incidentally, is shown more clearly in the 1971–72 data than in the 1970–71 data. That was what I mentioned earlier. In fact, in one analysis made of the data, the most consistent correlation occurred with suspended particulates including irritant respirable particulates.
>
> This does not necessarily mean that some oxides of sulfur are not deleterious to health. Rather, it implies that the health effects observed are probably due to a complex multipollutant mix of irritant respirable particulates consisting of sulfates, nitrates, organic and inorganic acids, et cetera, the sources of which are as complex as the mixture itself. There is no question that we just do not understand the nature of this complex mixture pollutant well enough today to either assign a safe threshold level or ascribe a cause/effect relationship to any or all components of the mixture. In the absence of such ability it is almost impossible to stipulate an effective control strategy for these pollutants.

The March 1976 House Appropriation hearings duplicated much of the information which had been provided the previous year. The 1976 planned program was modified slightly to indicate that the objectives on air health research were intended to focus studies toward selected population subgroups to describe health effects of exposure to sulfur oxides, respirable particulates and other pollutants as well as refining the data on acid sulfate aerosols. The general impression is one of reduction and refinement rather than expansion of surveillance programs. This impression is strengthened by examination of the proposed 1977 program which does include a number of objectives related to clarification of sulfate air chemistry and health effects. Again, no information is provided with regard to anticipated completion of final analysis of the remaining three years of data from the 1971–74 CHESS data.

To briefly recapitulate this legislative history, the CHESS programs evolved from smaller sets of epidemiological studies initiated well before the establishment of EPA. The concept of longitudinal health studies in selected cities to try to correlate health effects with air pollutants was a well established requirement prior to 1970. The phasing together of health indicators with real time measurements of air pollutants received more attention as the air monitoring capability became more available. The history does show that the execution of such epidemiological studies requires considerable preplanning and coordination; some of the studies have persisted for considerably longer periods of time than had been estimated for the data gathering, analysis, publication and utilization in policy planning. Associated with the evolution of the surveillance type health studies was a sequence of reorganizations and establishment of new organizations which undoubtedly produced significant management problems in maintaining continuity for projects requiring long term commitment of manpower and management attention. The CHESS program thus was essentially a continuous program, including many specific studies not originally contemplated as a part of a total system of programs. Reorganizations within EPA, such as the consolidation of laboratories at RTP under a different management system and significant restructuring of data processing systems are identified as other temporary obstacles to effective progress. It now appears that the epidemiological studies of the health effects of air pollutants have been somewhat restructured and reduced in scope to focus on specific subsets of populations for more specific objectives.

It is evident that the February 1976 Los Angeles Times series of articles on the 1974 CHESS report were preceded by a number of public discussions of the total problem of the health effects of sulfur oxides and including criticisms of the significance of the analyses in these reports. The 1974 CHESS monograph is actually a simultaneous publication of a number of studies of health effects of sulfur oxides, including some not actually a part of the health surveillance system known as CHESS. Critical evaluation of these analyses has been difficult as compared with the usual type of scientific peer review. Access to the data had been somewhat limited, and there was little time provided for review outside the writing team. Unlike most reports in scientific literature, the CHESS papers were not referreed in the usual manner nor are the epidemiological experiments readily repeated by individual independent researchers as is the case with more controlled experiments. Rather significant resources in air monitoring and data processing as well as in statistical analysis and collection of health effects information are required and for this reason, the studies represent a unique contribution to the literature. Nevertheless, experts in the field had drawn attention to several of their own misgivings about the conclusions of the CHESS reports. As discussed herein in more detail, the conclusions from epidemiological studies frequently are difficult to support in isolation but must be examined in the context of many other variables.

The task of evaluating the CHESS program then must include an understanding of the historical issues which identified the oxides of sulfur as a potential hazard to health, the problems of conducting epidemiological studies, and then an examination of the various scientific processes and management structures which were brought to bear upon the problem during the past 6–8 years. As noted in the Introduction to the Monograph, the purpose of the program was "to evaluate existing environmental standards, obtain health intelligence for new standards, and document the health benefits of air pollution control." It is this last task of defining benefits that requires a high degree of precision and for which maximum assurance must be present that the data being considered are indeed valid and not overinterpreted.

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Public Law 95-155
95th Congress

An Act

To authorize appropriations for activities of the Environmental Protection Agency, and for other purposes.

Nov. 8, 1977
[H.R. 5101]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Environmental Research, Development, and Demonstration Authorization Act of 1978".

Environmental Research, Development, and Demonstration Authorization Act of 1978.

Sec. 2. (a) There are authorized to be appropriated to the Environmental Protection Agency for environmental research, development, and demonstration activities for fiscal year 1978—

(1) $92,500,000 for water quality activities authorized under the Federal Water Pollution Control Act of which—

33 USC 1251 note.

(A) $25,200,000 is for the Health and Ecological Effects program;

(B) $9,300,000 is for the Industrial Processes program;

(C) $6,069,000 is for the Monitoring and Technical Support program;

(D) $22,300,000 is for the Public Sector Activities program; and

(E) $29,631,000 is for the Energy program.

(2) $10,800,000 for activities authorized under the Federal Insecticide, Fungicide, and Rodenticide Act, in the Health and Ecological Effects program.

7 USC 136 note.

(3) $16,000,000 for water supply activities authorized under the Safe Drinking Water Act, in the Public Sector program.

42 USC 300f note.

(4) $8,200,000 for toxic substance control activities authorized under the Toxic Substances Control Act, in the Health and Ecological Effects program.

15 USC 2601 note.

(5) $830,000 for radiation activities authorized under the Public Health Act, in the Health and Ecological Effects program.

42 USC 201 note.

(6) $35,000,000 for air quality activities authorized under the Clean Air Act, which shall be in addition to funds previously authorized in the Clean Air Act Amendments of 1977 (Public Law 95-95), so that the total amount authorized for such activities in fiscal year 1978 is $155,000,000, of which—

42 USC 1857 note.
Ante, p. 685.

(A) $36,000,000 is for the Health and Ecological Effects program;

(B) $11,000,000 is for the Monitoring and Technical Support program;

(C) $7,000,000 is for the Industrial Processes program; and

(D) $101,000,000 is for the Energy program.

(7) $31,273,000 for interdisciplinary activities, of which—

(A) $9,230,000 is for the Health and Ecological Effects program;

(B) $6,066,000 is for the Industrial Processes program;

(C) $1,599,000 is for the Public Sector Activities program; and

(D) $14,378,000 is for the Monitoring and Technical Support program.

(b) In addition to any other sums authorized by this section or by other provisions of law—

(1) there are authorized to be appropriated to the Administrator of the Environmental Protection Agency for fiscal year 1978, $10,000,000 for long-term research and development in accordance with section 6 of this Act;

(2) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $2,000,000 for training of health scientists needed for environmental research and development in fields where there are national shortages of trained personnel; and

(3) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $3,000,000 to implement the study authorized in section 103(d) of the Clean Air Act Amendments of 1977 (Public Law 95-95).

Ante, p. 687.

Appropriation authorization.

(c) There is authorized to be appropriated to the Administrator $19,000,000 for fiscal year 1978 for program management and support related to environmental research and development.

Transfer of funds, restriction.

(d) No funds may be transferred from any particular category listed in subsection (a) or (b) to any other category or categories listed in either such subsection if the total of the funds so transferred from that particular category would exceed 10 per centum thereof, and no funds may be transferred to any particular category listed in subsection (a) or (b) from any other category or categories listed in either such subsection if the total of the funds so transferred to that particular category would exceed 10 per centum thereof, unless—

(1) a period of thirty legislative days has passed after the Administrator of the Environmental Protection Agency or his designee has transmitted to the Speaker of the House of Representatives and to the President of the Senate a written report containing a full and complete statement concerning the nature of the transfer and the reason therefor, or

(2) each committee of the House of Representatives and the Senate having jurisdiction over the subject matter involved, before the expiration of such period, has transmitted to the Administrator written notice to the effect that such committee has no objection to the proposed action.

Sec. 3. Appropriations made pursuant to the authority provided in section 2 of this Act shall remain available for obligation for expenditure, or for obligation and expenditure, for such period or periods as may be specified in the Acts making such appropriations.

Budget projections.
42 USC 4361a.
42 USC 4361.

Sec. 4. The Administrator of the Environmental Protection Agency, in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94-475, shall include budget projections for a "no-growth" budget, for a "moderate-growth" budget, and for a "high-growth" budget. In addition, each such annual revision shall include a detailed explanation of the relationship of each budget projection to the existing laws which authorize the Administration's environmental research, development, and demonstration programs.

Public sector agencies, grants.
42 USC 300j-3a.

Sec. 5. (a) The Administrator of the Environmental Protection Agency shall offer grants to public sector agencies for the purposes of—

(1) assisting in the development and demonstration (including construction) of any project which will demonstrate a new or improved method, approach, or technology for providing a dependably safe supply of drinking water to the public; and

(2) assisting in the development and demonstration (including construction) of any project which will investigate and demonstrate health and conservation implications involved in the reclamation, recycling, and reuse of wastewaters for drinking and the processes and methods for the preparation of safe and acceptable drinking water.

Grants, limitations.

(b) Grants made by the Administrator under this section shall be subject to the following limitations:

(1) Grants under this section shall not exceed 66⅔ per centum of the total cost of construction of any facility and 75 per centum of any other costs, as determined by the Administrator.

(2) Grants under this section shall not be made for any project involving the construction or modification of any facilities for any public water system in a State unless such project has been approved by the State agency charged with the responsibility for safety of drinking water (or if there is no such agency in a State, by the State health authority).

(3) Grants under this section shall not be made for any project unless the Administrator determines, after consultation, that such project will serve a useful purpose relating to the development and demonstration of new or improved techniques, methods, or technologies for the provision of safe water to the public for drinking.

(c) There are authorized to be appropriated for the purposes of this section $25,000,000 for fiscal year 1978.

Research and development program.
42 USC 4363.

SEC. 6. (a) The Administrator of the Environmental Protection Agency shall establish a separately identified program to conduct continuing and long-term environmental research and development. Unless otherwise specified by law, at least 15 per centum of any funds appropriated to the Administrator for environmental research and development under section 2(a) of this Act or under any other Act shall be allocated for long-term environmental research and development under this section.

Report to President and Congress.

Contents.

(b) The Administrator, after consultation with the Science Advisory Board, shall submit to the President and the Congress a report concerning the desirability and feasibility of establishing a national environmental laboratory, or a system of such laboratories, to assume or supplement the long-term environmental research functions created by subsection (a) of this section. Such report shall be submitted on or before March 31, 1978, and shall include findings and recommendations concerning—

(1) specific types of research to be carried out by such laboratory or laboratories;

(2) the coordination and integration of research to be conducted by such laboratory or laboratories with research conducted by existing Federal or other research facilities;

(3) methods for assuring continuing long-range funding for such laboratory or laboratories; and

(4) other administrative or legislative actions necessary to facilitate the establishment of such laboratory or laboratories.

42 USC 4364.

SEC. 7. (a) The Administrator of the Environmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or any other provision of law for environmental research and development related to regulatory program activities shall be coordinated with and reflect the research needs and priorities of the program offices, as well as the overall research needs and priorities of the Agency, including those defined in the five-year research plan.

Program offices.

(b) For purposes of subsection (a), the appropriate program offices are—

(1) the Office of Air and Waste Management, for air quality activities;

(2) the Office of Water and Hazardous Materials, for water quality activities and water supply activities;

(3) the Office of Pesticides, for environmental effects of pesticides;

(4) the Office of Solid Waste, for solid waste activities;

(5) the Office of Toxic Substances, for toxic substance activities;

(6) the Office of Radiation Programs, for radiation activities; and

(7) the Office of Noise Abatement and Control, for noise activities.

Report to President and Congress.

(c) The Administrator shall submit to the President and the Congress a report concerning the most appropriate means of assuring, on a continuing basis, that the research efforts of the Agency reflect the needs and priorities of the regulatory program offices, while maintaining a high level of scientific quality. Such report shall be submitted on or before March 31, 1978.

Science Advisory Board.
Establishment.
42 USC 4365.

SEC. 8. (a) The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as the Administrator requests.

Membership.

(b) Such Board shall be composed of at least nine members, one of whom shall be designated Chairman, and shall meet at such times and places as may be designated by the Chairman of the Board in consultation with the Administrator. Each member of the Board shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board under this section.

(c) In addition to providing scientific advice when requested by the Administrator under subsection (a), the Board shall review and comment on the Administration's five-year plan for environmental research, development, and demonstration provided for by section 5 of Public Law 94-475 and on each annual revision thereof. Such review and comment shall be transmitted to the Congress by the Administrator, together with his comments thereon, at the time of the transmission to the Congress of the annual revision involved.

42 USC 4361.

Report to Administrator, President, and Congress.

(d) The Board shall conduct a review of and submit a report to the Administrator, the President, and the Congress, not later than October 1, 1978, concerning—

(1) the health effects research authorized by this Act and other laws;

(2) the procedures generally used in the conduct of such research;

(3) the internal and external reporting of the results of such research;

(4) the review procedures for such research and results;

(5) the procedures by which such results are used in internal and external recommendations on policy, regulations, and legislation; and

(6) the findings and recommendations of the report to the House Committee on Science and Technology entitled "The

Environmental Protection Agency's Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report".

The review shall focus special attention on the procedural safeguards required to preserve the scientific integrity of such research and to insure reporting and use of the results of such research in subsequent recommendations. The report shall include specific recommendations on the results of the review to ensure scientific integrity throughout the Agency's health effects research, review, reporting, and recommendation process.

(e)(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource, Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, or the Safe Drinking Water Act, or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.

42 USC 1857 note.
33 USC 1251 note.
42 USC 6901 note.
42 USC 4901 note.
15 USC 2601 note.
42 USC 300f note.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

(f) In preparing such advice and comments, the Board shall avail itself of the technical and scientific capabilities of any Federal agency, including the Environmental Protection Agency and any national environmental laboratories.

Member committees and investigative panels.

(g) The Board is authorized to constitute such member committees and investigative panels as the Administrator and the Board find necessary to carry out this section. Each such member committee or investigative panel shall be chaired by a member of the Board.

Secretary, appointment.

(h)(1) Upon the recommendation of the Board, the Administrator shall appoint a secretary, and such other employees as deemed necessary to exercise and fulfill the Board's powers and responsibilities. The compensation of all employees appointed under this paragraph shall be fixed in accordance with chapter 51 and subchapter III of chapter 53 of title 5 of the United States Code.

5 USC 5101, 5331.

(2) Members of the Board may be compensated at a rate to be fixed by the President but not in excess of the maximum rate of pay for grade GS-18, as provided in the General Schedule under section 5332 of title 5 of the United States Code.

5 USC 5332 note.

(i) In carrying out the functions assigned by this section, the Board shall consult and coordinate its activities with the Scientific Advisory Panel established by the Administrator pursuant to section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

7 USC 136w.
42 USC 4366.

Sec. 9. (a) The Administrator of the Environmental Protection Agency, in consultation and cooperation with the heads of other Federal agencies, shall take such actions on a continuing basis as may be necessary or appropriate—

(1) to identify environmental research, development, and demonstration activities, within and outside the Federal Govern-

ment, which may need to be more effectively coordinated in order to minimize unnecessary duplication of programs, projects, and research facilities;

(2) to determine the steps which might be taken under existing law, by him and by the heads of such other agencies, to accomplish or promote such coordination, and to provide for or encourage the taking of such steps; and

(3) to determine the additional legislative actions which would be needed to assure such coordination to the maximum extent possible.

Report.
42 USC 4361.

The Administrator shall include in each annual revision of the five-year plan provided for by section 5 of Public Law 94-475 a full and complete report on the actions taken and determinations made during the preceding year under this subsection, and may submit interim reports on such actions and determinations at such other times as he deems appropriate.

(b) The Administrator of the Environmental Protection Agency shall coordinate environmental research, development, and demonstration programs of such Agency with the heads of other Federal agencies in order to minimize unnecessary duplication of programs, projects, and research facilities.

(c)(1) In order to promote the coordination of environmental research and development activities, and to assure that the action taken and methods used (under subsection (a) and otherwise) to bring about such coordination will be as effective as possible for that purpose, the Council on Environmental Quality in consultation with the Office of Science and Technology Policy shall promptly undertake and carry out a joint study of all aspects of the coordination of environmental research and development. The Chairman of the Council shall prepare a report on the results of such study, together with such recommendations (including legislative recommendations) as he deems appropriate, and shall submit such report to the President and the Congress not later than May 31, 1978.

Report to President and Congress.
Legislative recommendations.
Presidential report to Congress.

(2) Not later than September 30, 1978, the President shall report to the Congress on steps he has taken to implement the recommendations included in the report under paragraph (1), including any recommendations he may have for legislation.

42 USC 4361b.

SEC. 10. The Administrator of the Environmental Protection Agency shall implement the recommendations of the report prepared for the House Committee on Science and Technology entitled "The Environmental Protection Agency Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report", unless for any specific recommendation he determines (1) that such recommendation has been implemented, (2) that implementation of such recommendation would not enhance the quality of the research, or (3) that implementation of such recommendation will require funding which is not available. Where such funding is not available, the Administrator shall request the required authorization or appropriation for such implementation. The Administrator shall report the status of such implementation in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94-475.

Personnel positions, increase.

SEC. 11. The Administrator of the Environmental Protection Agency shall increase the number of personnel positions in the Health and Ecological Effects program to 862 positions for fiscal year 1978.

Annual statement, filing.
42 USC 4367.

SEC. 12. (a) Each officer or employee of the Environmental Protection Agency who—

(1) performs any function or duty under this Act; and

(2) has any known financial interest in any person who applies for or receives grants, contracts, or other forms of financial assistance under this Act,

shall, beginning on February 1, 1978, annually file with the Administrator a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be available to the public.

(b) The Administrator shall—

(1) act within ninety days after the date of enactment of this Act—

(A) to define the term "known financial interest" for purposes of subsection (a) of this section; and

(B) to establish the methods by which the requirement to file written statements specified in subsection (a) of this section will be monitored and enforced, including appropriate provision for the filing by such officers and employees of such statements and the review by the Administrator of such statements; and

Report to Congress.

(2) report to the Congress on June 1 of each calendar year with respect to such disclosures and the actions taken in regard thereto during the preceding calendar year.

(c) In the rules prescribed under subsection (b) of this section, the Administrator may identify specific positions of a nonpolicymaking nature within the Administration and provide that officers or employees occupying such positions shall be exempt from the requirements of this section.

Violation, penalty.

(d) Any officer or employee who is subject to, and knowingly violates, this section, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

Paperwork minimization, encouragement.

SEC. 13. It is the national policy that to the maximum extent possible the procedures utilized for implementation of this Act shall encourage the drastic minimization of paperwork.

Approved November 8, 1977.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 95-157 (Comm. on Science and Technology) and No. 95-722 (Comm. of Conference).
SENATE REPORT No. 95-188 accompanying S. 1417 (Comm. on Environment and Public Works).
CONGRESSIONAL RECORD, Vol. 123 (1977):
  Apr. 19, considered and passed House.
  May 27, considered and passed Senate, amended, in lieu of S. 1417.
  Oct. 20, Senate agreed to conference report.
  Oct. 25, House agreed to conference report.

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Part 2

EPA's annual reports to Congress on the Agency's five-year plans for research and development, as required by Section 10 of ERDDAA.

APPENDIX E

CHESS--The Community Health and Environmental Surveillance System--Congressional Recommendations--Status Report II

Background: A controversy about the scientific credibility of results from the CHESS study prompted a series of congressional hearings in 1976. Subsequently, 17 major recommendations were made by Congress to EPA regarding methods and means to upgrade its environmental research. These recommendations covered a wide spectrum of subjects. Public Law 95-155, the Environmental Research, Development and Demonstration Authorization Act of 1978 specified that EPA annually report on the implementation status of each recommended action. This report is the second status report; the first was in *Research Outlook 1978.*

Because last year's report was the first status report, it included descriptions of all the recommendations and subsequent EPA actions. The reader is referred to that report and documents in the bibliography for detailed information about the recommendations. Given below is a status update of only those EPA actions taken last year.

Recommendation 3--CHESS Monograph

This recommendation concerns the public access to and understanding of the limitations of the CHESS monograph. To comply, we have sent an appropriate cover letter and copies of the *Research Outlook 1978* (which contains the first status report on the CHESS recommendations) to locatable holders of the CHESS monograph. Any additional copies of the CHESS monograph that are distributed will be accompanied by copies of the cover letter and the *Research Outlook 1978.* Finally, a notice is planned for the *Federal Register* informing the public of the availability of further information on the CHESS monograph. These actions, we believe, satisfy the intent of recommendation 3.

Recommendations 10(a), 10(c) and 12(a)

These recommendations concern peer review of EPA's scientific research. The subject has received increased attention in various quarters of EPA in the past year.

To improve the quality of research throughout ORD, the EPA Assistant Administrator for Research and Development has directed establishment of peer review mechanisms at the laboratory level. He has also directed the headquarters line managers, to whom the laboratories report, to structure a headquarters level peer review. Submission of ORD research results to referred scientific journals is also being stressed.

The EPA Science Advisory Board (SAB) is a prime source for peer review of research and research program planning advice. Its various components regularly examine elements of ORD's research program.

Recommendation 10(a) specifically concerns establishment of an interdisciplinary task force to draw up a plan for EPA to develop "a solid base of knowledge and procedures in aerometric instrumentation and measurements, meteorology, field data gathering, quality control, epidemiology project design, and testing and panel planning." Last year's status report indicated that this recommendation would be discussed with the EPA's Science Advisory Board. The Board's Health Effects Research Committee was directed by Public Law 95-155, the Research, Development and Demonstration Act of 1978, to review EPA's health effects research, including the recommendations of the CHESS Investigative Report. The Committee is in the process of completing its report. We await that report, and the recommenda-

RESOLUTION OF INVESTIGATIVE REPORT RECOMMENDATIONS

Number	Summary of Recommendations	Action
3(a)	EPA should publish an announcement regarding the limitations of the CHESS Monograph	Implemented
3(b)	EPA should not use the CHESS Monograph without explicit qualification	Implemented
3(c)	EPA should publish an addendum to the CHESS Monograph including most of the Investigative Report	Implemented
4(a)	Legislation should be reexamined regarding unrealistic procedures and schedules	Implemented
4(b)	EPA should design research to gain information and not support positions	Implemented
4(c)	OMB should allow all necessary resources if public policy requires expeditious research	Implemented
4(d)	EPA should advise Congress if budgetary restrictions will impact completion of major projects	Implemented
5	OMB should be asked to develop procedures for prompt review of questionnaire	Implemented
6(a)	CHESS date analyses should be carried out only on data with high validity potential	Implemented
6(b)	EPA should publish research in referred journals in a timely fashion	Implemented
6(c)	EPA should not publish large projects solely in monograph form	Implemented
6(d)	EPA should not initiate projects for policy consideration unless they can be completed in a realistic time frame	Implemented
7(a)	EPA should strengthen the CHAMP aerometric and quality control programs	Implemented
7(b)	EPA should shorten the time between data acquisition and quality assurance analysis of data	Implemented
7(c)	EPA should stop employing development stage instruments before qualification testing	Implemented
7(d)	EPA should not use laboratory models of instruments in the field until they have been field checked and operating personnel trained	Implemented
7(e)	EPA should reevaluate the opening of the CHAMP operations contract to competition	Implemented
7(f)	EPA research and monitoring personnel should closely coordinate regarding chemical species	Implemented
8	EPA should have additional meteorological support for air pollution health effects research studies	Implemented
9	EPA should examine accelerating research in pollutant characterization	Implemented
10(a)	An interdisciplinary task force should draw up an integrated air epidemiology-exposure assessment program plan for EPA	Implemented
10(b)	CHAMP should verify instruments and protocols so that reliable data can be achieved	Implemented
10(c)	EPA should have epidemiological questionnaires and panel selection criteria approved by peer groups	Implemented
10(d)	EPA should review research concepts obtained from team interviews	Implemented
11	The Environmental Resarch Center at Research Triangle Park (RTP) should not be reorganized until the end of FY 77	Implemented
12(a)	EPA should establish authoritative peer review panels to assist in improving research coordination	Implemented
12(b)	EPA should have a stronger focus on management at the Environmental Resarch Center, RTP	Implemented
12(c)	EPA should create a systems analysis-operations research program review group	Implemented
12(d)	The Science Advisory Board's charter should be expanded	Implemented
13(a)	EPA should seek cooperative research programs with universities and other laboratories and agencies	Implemented
13(b)	EPA should promote the exchange of scientists within and outside the Agency	Implemented
13(c)	EPA should fund individual Ph.D. thesis research	Under consideration

(CONT.)

Number	Summary of Recommendations	Action
13(d)	The Science Advisory Board should develop outreach programs	Under consideration
14	The Administrator should clarify the role of the Office of Research and Development and its laboratories	Shall be implemented
15	EPA should resolve the separation of facilities at RTP	Under consideration
16	EPA should develop a professional career development program for each professional employee	Implemented
17	The Administration should determine if EPA should conduct research under its present organizational configuration	Implemented

Source: Research Outlook 1978

tions of the Committee's Subcommittee on Epidemiologic Studies. We will take appropriate action based on the recommendations.

Recommendation 10(c) concerns peer review and approval of epidemiological questionnaires and panel selection criteria. Appropriate review and approval are part of the review of epidemiology studies in EPA's research program, conducted by the SAB's Health Effects Research Review Committee. It should be noted that the Interagency Regulatory Liaison Group (IRLG), composed of EPA, OSHA, CPSC, and FDA has a working group on epidemiology. A subgroup addresses standards which would apply to epidemiological studies in order to assure scientific validity for use as court evidence.

Recommendation 12(a) refers to peer review panels for increased coordination of research. The review responsibilities of the Committees mentioned in recommendations 10(a) and 10(c) fulfill this recommendation. In addition, improved peer review of EPA research was incorporated within a new research planning system established within the past year to improve the responsiveness of ORD to EPA program offices. This subject is discussed in two reports to Congress: "The Planning and Management of Research and Development Activities Within EPA," June 1978, and a follow-up status report in December 1978.

These reports describe research planning via specially formed research committees. Each committee will consist of representatives from ORD and EPA Program Offices, and will plan research specific to those offices. The new research planning system calls for incorporation of peer review mechanisms throughout the planning and management process in order to improve research quality. Several research committees have been operating successfully on a pilot basis, and more are planned. While systematic peer review has not yet been implemented in the pilot committees, EPA hopes to do so within the coming months.

Recommendations 13(a), 13(c) and 13(d)

These recommendations address a perceived isolation of EPA research. They concern technical information exchange and interaction of EPA scientists with peers outside EPA, particularly with the university community.

Last year's status report described EPA's ties with the university community, mentioning, most notably, EPA extramural research which involves grants with universities. In FY 1977, EPA awarded 618 grants to 355 academic institutions. Each grant is monitored by an EPA project officer, an arrangement enabling our people to work closely with researchers outside EPA.

Additionally, the Intergovernmental Personnel Act has allowed an exchange of researchers between EPA and state and local governments and universities. A report to Congress, "Laboratories Needed to Support Long-Term Research in EPA," April 1978, further explores possible ties between ORD and universities. The report recommends a selectively expanded program of long-range research with both intramural and extramural components. An important means of assuring coordination of these components is scientist-to-scientist contact between EPA and the academic community. The extramural portion of the program would initially be a series of small centers for long-range research at universities and other institutions dedicated to specific research problems. In FY 1979, ORD will propose three such centers, one each for advanced control technology, epidemiology, and groundwater research. These centers would serve as bridges to the academic community and should provide ORD with a reservoir of talented scientists.

ORD's Minority Institutions Research Support (MIRS) program also serves the spirit of recommendation 13. MIRS was established in 1972 to help minority institutions develop the potential for conducting environmental research and thus become more competitive for federal funds. The EPA's MIRS staff maintains continual liaison between university researchers and the ORD scientific staff to develop relevant research proposals. Some expansion of the program is being considered.

Recommendation 13(c) refers specifically to EPA programs to fund individual PhD theses. EPA's workforce training program, recently placed under ORD's aegis, includes both academic training grants given to various institutions and fellowships to individuals. EPA's role in this type of program is unique since many whose work is crucial to achieve environmental goals are not directly employed by EPA. This nonfederal workforce includes wastewater treatment operators, state environmental employees, and other professionals. EPA currently is working with the Department of Labor and the Office of Education to address various options for further workforce development.

Recommendation 13(d) concerns Science Advisory Board assistance to EPA to develop an outreach program. We have actively sought SAB counsel for many activities related to our connections with the academic community. For example, the SAB helped prepare the report cited above, "Laboratories Needed to Support Long-Term Research in EPA." Additionally, the EPA Assistant Administrator for Research and Development made a formal presentation to SAB concerning ORD's university relations. As a result of this presentation and previous discussion, the SAB will develop outreach program suggestions for further consideration.

Recommendations 14 and 17

These recommendations state that the EPA Administrator should clarify the role of the EPA Office of Research and Development and determine if research should be conducted in its present organizational configuration.

The Environmental Research, Development and Demonstration Act of 1978 (Public Law 95-155) directed the EPA Administrator to report to the President and Congress the most appropriate means of assuring that EPA's research efforts reflect the needs and priorities of the EPA regulatory program offices. The EPA Administrator fulfilled that mandate with the distribution of the report "The Planning and Management of Research and Development Activities within EPA" (June 1978). The information in this report satisfies both recommendations.

Concerning Recommendation 14—the clarification of the role of ORD and its laboratories—the report provided a mechanism for improved coordination between ORD and program offices for planning research. This mechanism, described above in connection with peer review, is a series of research committees, established for each research planning unit. Five pilot committees have already been established for key research areas and more are planned. Each research committee is chaired by a research manager (designated by ORD) and has representatives from relevant program offices and EPA Regions. At a hearing before the House Science and Technology Committee, Subcommittee on the Environment and the Atmosphere, the EPA Administrator and Assistant Administrators attested to the success of this approach. A formal status report on the pilot activities was provided to ORD's authorizing committees in December, 1978.

Further exploration of ORD's role in the Agency was provided by the report mentioned under Recommendation 13. This report, "Laboratories Needed to Support Long-Term Research in EPA" (April 1978) examines alternative approaches for conducting long-term environmental research and presents findings and recommendations. The report also reviews the history of ORD laboratories, describes representative research areas that could benefit from enhanced long-term support, describes mechanisms used by other federal agencies for carrying out this kind of research, and presents options for long-term research within EPA.

Concerning Recommendation 17—that EPA determine whether it should conduct research under its present organizational configuration—a study group found that "the Agency's R&D problems have not resulted from the way the R&D program is organized." To reach this conclusion, the group reviewed a number of similar organizational structures in various federal agencies. Possible use of some of those organizational structures was rejected and, instead, the study group proposed for ORD the management system changes described above.

Recommendation 15

This recommendation directs EPA to resolve the separation of facilities at Research Triangle Park (RTP), North Carolina. EPA's Office of Research and Development (ORD) is presently preparing a program of requirements for a new research and development facility at Research Triangle Park. Additionally, the Agency has set up an EPA long-range plan for special purpose facilities. This long-range plan would be agency-wide and would include the EPA regional offices' facilities as well as the Office of Research and Development laboratories.

CHESS

Health Consequences of Sulfur Oxides: A Report from CHESS, 1970-1971. United States Environmental Protection Agency. EPA 650/1-74-004. May, 1974.

Laboratories Needed to Support Long-Term Research in EPA: A Report to the President and the Congress. United States Environmental Protection Agency. EPA 600/8-78-003. April, 1978.

Pilot Study of the Revised Planning and Management System for Research and Development in the Environmental Protection Agency: A Status Report to the Congress. United States Environmental Protection Agency. November, 1978.

Report of the Task Force to Review CHESS. United States Environmental Protection Agency. April 7, 1976.

Report on Joint Hearings on the Conduct of the Environmental Protection Agency's Community Health and Environmental Surveillance System' (CHESS) Studies. United States Congress. House Interstate and Foreign Commerce and House Science and Technology Committee. 94th Congress, 2nd Session. Washington, United States Government Printing Office, April, 1976.

Report on the Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS). United States Congress. House Committee on Science and Technology Committee. 94th Congress, 2nd Session. Washington, United States Government Printing Office, November, 1976.

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Rood, W.B. EPA Study—The Findings Got Changed. Los Angeles Times, February 29, 1976.

The Planning and Management of Research and Development Within EPA: A Report to the President and the Congress. United States Environmental Protection Agency. June 30, 1978.

☆ U.S. GOVERNMENT PRINTING OFFICE 1979 O—291-1

Appendix 3

Community health and environmental surveillance system

3

Introduction

On November 24, 1976, the House Subcommittee on the Environment and Atmosphere of the Committee on Science and Technology released a report titled, "The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report" (Ref. 1). The Environmental Research, Development, and Demonstration Authorization Act of 1978 (P.L. 95-155) specifies that EPA shall report the implementation status of the Investigative Report's recommendations in each annual revision of its five-year plan. This is the first EPA implementation status report.

Background

CHESS emerged as a major program in 1970. A discussion of goals and objectives is in "Environmental Science and Technology" (Ref. 2). CHESS was designed, as the name indicates, to monitor the health status of the United States population with respect to varying environmental conditions. For the most part, the environmental considerations were limited to meteorologic conditions and pollution levels. The program included studies of health groups and potentially susceptible groups such as asthmatics. CHESS data, gathered over five years, have been analyzed for relationships between health effects and exposure to such pollutants as sulfur oxides, nitrogen oxides, particulate matter, and oxidants.

In May 1974, EPA published the "Health Consequences of Sulfur Oxides: A Report from CHESS, 1970-1971" (often referred to as the CHESS Monograph) that included several of the early CHESS aerometric and health studies (Ref. 3).

On February 29, 1976 the *Los Angeles Times* published the first of several articles implying that studies in the CHESS Monograph on the health effects of ambient sulfur oxides were distorted (Ref. 4). Basically, the *Times* articles made three allegations: (1) the analysis of the CHESS data shows a stronger than actual correlation of adverse health effects with increased levels of ambient sulfate; (2) Dr. John F. Finklea was responsible for the distortion, with the passive assistance of his subordinates; and (3) the EPA regulatory program for sulfur oxides rests solely on the CHESS program.

On April 7, 1976, an EPA investigative task force appointed to review the entire matter reported its findings (Ref. 5). This group interviewed most of the EPA employees who participated in the CHESS data analysis. From these interviews, it became apparent that comments of EPA personnel made to the *Times* reporter referred to the 1972 draft version of the report, and not to the final publication of 1974. The group's unanimous opinion concerning both the draft and final versions was "that there is no evidence of dishonesty or deliberate distortion of data by Dr. John F. Finklea or members of his staff who worked on the Monograph. On the contrary, there is evidence of an honest and aggressive effort to publish the sulfur oxide findings from the CHESS studies so that they would be available in a timely fashion for use by the Agency and the public at large."

On April 9, 1976, the allegations concerning the CHESS report and the *Times* articles were the subject of a Congressional hearing convened by two House Committees: Science and Technology and Interstate and Foreign Committee (Ref. 6, pp. 23-24). Three of the Committees' conclusions, which directly relate to the *Los Angeles Times* allegation, are:

- "There was agreement that the CHESS studies confirm an association between sulfur oxides emissions and adverse health effects."
- "There was no evidence that Dr. Finklea tampered with, distorted, or withheld data."
- "The National Ambient Air Quality Standards (NAAQS) for sulfur dioxide were set before CHESS, and were based on other data."

An examination of the *Times* articles and the Congressional hearing is published in *Science* and the *Environmental Health Letter* (Ref. 7, 8).

The House Committee on Science and Technology started an investigation concerning technical issues relating to CHESS in April of 1976. The Committee released the Investigative Report on November 24, 1976 (Ref. 1).

Investigative report recommendations

The recommendations in the Investigative Report concern two major topics: the scientific assessment of the CHESS program, and the present and future management of EPA research. EPA agrees with many of the Investigative Report's statements and recommendations regarding the quantitative limitations of the CHESS results. Also, EPA concurs with the majority of the recommendations for the improvement of research. The implementation status for each recommendation is discussed in the following paragraphs.

Recommendation 3
CHESS Monograph

Recommendations 3(a), (b), and (c) in the Investigative Report concern the CHESS Monograph. Recommendation 3(b) directs that the Monograph should not be used without explicit qualifications. Recommendations 3(a) and 3(c) state that EPA should publish an announcement regarding the limitations of the Monograph and publish an addendum to the Monograph (including at least Chapters IV, V, VI, and Appendix A of the Investigative Report). Prior to presenting our response to these recommendations, the EPA air health effects research program, the CHESS Monograph, and EPA's regulatory responsibilities will be placed in perspective.

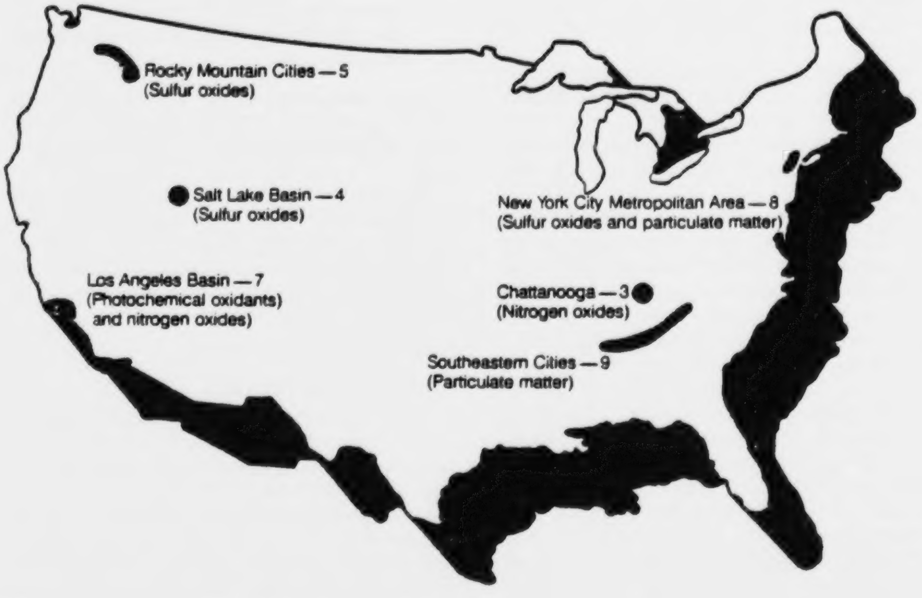
The air health effects research program uses a combination of research approaches: human epidemiological studies, human clinical studies, and toxicological studies on animal models (Ref. 9). Integrating the capabilities and advantages of these approaches provides the best overall scientific strategy for informed regulatory decisions. Concerning the CHESS program, epidemiologic investigations offer the advantages of studying the biological responses of people, including vulnerable groups, under ambient conditions.

The major problems are related to quantifying the exposure, dealing with many typically unknown covariates, and interpreting association vs. causation. Several publications, including the Investigative Report, contain detailed explanations of the strengths and weaknesses of epidemiology (Ref. 1, pp. 57-58; Ref. 10, pp. 16-17; Ref. 11, pp. 16-17).

EPA acknowledges the limitations of individual epidemiologic studies. For example, the Summary and Conclusions of the CHESS Monograph states:

> "The findings summarized in this paper must be substantiated by replicated observations in different years and under different circumstances. Well controlled human and animal studies are required to isolate several of the important intervening variables that are inherent to studies of free living populations, and to elucidate the precise nature of the pollutant-disease relationship. Hence, the conclusions put forth at this time cannot be definitive, but are offered in the sense of developing more refined quantitative and scientific hypotheses concerning pollutant-health effect associa-

CHESS Study Areas


Rocky Mountain Cities — 5
(Sulfur oxides)
Salt Lake Basin — 4
(Sulfur oxides)
New York City Metropolitan Area — 8
(Sulfur oxides and particulate matter)
Los Angeles Basin — 7
(Photochemical oxidants)
and nitrogen oxides)
Chattanooga — 3
(Nitrogen oxides)
Southeastern Cities — 9
(Particulate matter)

Note: Numbers indicate number of neighborhoods studied per area tions in a real life environment." (Ref. 3, p. 7-4).

Most epidemiologic studies are open to criticism and this was the reason spatial and temporal replication was fundamental to the CHESS designs. Further, in practically all areas of epidemiology, conclusions rest on the weight of evidence from many studies, not on individual studies. Thus, there is ample justification to cite CHESS studies as they bear on existing EPA standards. An important feature of several of the CHESS studies reported in the Monograph is their general consistency with the majority of epidemiologic, clinical, and toxicologic studies previously published in the sulfur oxides and particulate matter literature. The CHESS studies tend to support the reasonableness of existing ambient air quality standards for sulfur oxides and particulate matter. However, EPA agrees that there is far too much uncertainty and lack of qualification in findings contained in the Monograph to support any new or modified air quality standards.

Finally, the Monograph assessments of current pollution exposure were among the most complete that had ever been performed within the then existing state-of-the-art. These epidemiologic findings, although having a limited ability to affect EPA regulatory policy, have materially advanced our knowledge concerning the general distribution and behavior of the exposure-response variables employed.

Misunderstandings still exist, however, over the CHESS Monograph and EPA's regulatory posture on sulfur oxides. Therefore, this report to the Congress shall be widely circulated and sent to all holders of the CHESS Monograph with an appropriate cover letter. With this action, EPA believes that the intent of Recommendation 3 will be adequately implemented.

Recommendation 4 research responsibilities

Recommendation 4 addresses research responsibilities and resources. Recommendation 4(a) directs that legislation should be reexamined regarding unrealistic procedures and schedules. Legislative mandates are the most important considerations in the annual program planning process. EPA maintains an in-house research capability and expertise to respond to short deadlines. However, when procedures or schedules are unrealistic, the Congress and the Office of Management and Budget (OMB) are informed by either the normal budget submission process, during oversight hearings, or by other appropriate mechanisms. Recommendation 4(b) specifies that research be designed to gain information and not support positions. The Office of Research and Development is organizationally separated from offices having regulatory responsibilities. Therefore, scientists conduct research to gain accurate information and are not under pressure to support existing or preconceived positions held by the regulatory offices. The Science Advisory Board, an independent advisory body, has established a Subcommittee on Epidemiological Studies to independently review EPA's epidemiology (Ref. 12). Recommendations 4(c) and (d) concern the Office of Management and Budget allowing all necessary funding for expeditious research and advising the Congress of budgetary restrictions affecting completion of major projects. Through the normal budgetary process, the Office and the Congress are advised for EPA resource requirements and which programs are affected by budgetary restrictions.

Recommendation 5 questionnaires

Recommendation 5 advises that the OMB should be asked to develop procedures for prompt review of questionnaires. OMB and EPA's research managers and scientists have discussed this matter. These discussions have expedited questionnaire clearances. However, the total number of questionnaires allocated to EPA is small and therefore limits the number of epidemiologic studies that can be performed (Ref. 13). The control of questionnaires by the Federal Government was intended to reduce involuntary solicitations from the private sector. Only selected volunteers participate in EPA's epidemiologic studies. Therefore, we believe that EPA's voluntary questionnaires should be free of allocation limitations.

Recommendation 6 CHESS data

Recommendation 6 concerns the processing and publication of the remaining CHESS data. Recommendation 6(a) directs that unanalyzed data be examined and that analyses be carried out on those data that appear to have a higher degree of validity than the CHESS Monograph data base. In general, the quality of the CHESS data improved as experience was gained. Therefore, a plan has been developed for validation of 61 of the 65 data sets for which reports have not yet been published (Ref. 14). Four episode studies will not be validated because their usefulness is questionable. Recommendations 6(b) and (c) concern publishing research in traditional, refereed, archival, journals and not publishing solely in monograph form. EPA endorses this policy. Independent university scientists are being used to analyze, interpret, and report on appropriate CHESS data. Manuscripts of research investigations are being submitted for publication in the scientific literature as relevant studies are completed. As of December 1, 1977, there have been 28 CHESS publications in scientific journals (Ref. 15). Monographs are, and have mainly been, used as a vehicle to present all pertinent data that would be inappropriate for publication in scientific journals. Recommendation 6(d) states that projects for policy considerations should not be initiated unless they can be completed in a realistic time frame and unless the research staff can be involved in the process. Several mechanisms have been incorporated to develop achievable program plans. These include a joint program planning process where the staffs of the research laboratories and headquarters, and the program offices participate. In addition, laboratory program reviews are conducted and problems associated with the implementation of investigations are discussed and resolved.

Recommendations 7, 8, and 10(b)—CHAMP

Recommendations 7, 8, and 10(b) are directed toward CHAMP, EPA's Community Health Air Monitoring Program. Recommendation 7(a) states that the aerometric and quality control programs should be further strengthened and improved. An expanded quality control program is being implemented in EPA (Ref. 16). Specifically for CHAMP, comparisons for instruments, techniques, and standards are being conducted among the EPA laboratories measuring air quality. In addition, a contractor is providing additional quality control audits of the CHAMP field and laboratory systems (Ref. 17). This includes the use of National Bureau of Standards flow and measurement standards as well as gas mixture standards. Recommendation 7(b) directs a shortening of time between data acquisition and quality assurance analysis of data. The new CHAMP contractor has been given technical direction to minimize the time between data collection and validation (Ref. 18). To accomplish this, software is being developed and maintenance practices have been revised.

Recommendations 7(c) and (d) specify that development stage instruments should not be employed before qualification testing has been done and that laboratory models of instruments should not be used in the field until they have been field checked and operating personnel have been trained. The present CHAMP policy calls for complete checkout, acceptance testing, and personnel training before field placement of any developmental stage instruments. Recommendation 7(e) directs that the opening of the CHAMP operations contract to competition should be reexamined to see whether the merits of open bidding outweigh the problems of instability. This reevaluation took place and it was determined that the merits of open bidding with the possibility of improved performance outweighed any problems of instability. In due course, the contract was awarded to a new contractor after competitive bidding. The transition period between the old and new contractors disclosed several major deficient areas. This finding confirmed the wisdom of the decision to reopen the CHAMP operations contract. Recommendation 7(f) concerns health effects personnel closely coordinating with air quality and monitoring personnel to understand chemical species to be monitored. The CHAMP staff is cooperating closely with the epidemiologists and other health scientists in the design and protocol development for epidemiologic studies. This cooperation includes reaching mutual agreement on chemical species to be monitored.

Recommendation 8 concerns additional meteorological support for health research-air pollution effects studies. This recommendation also directs that meteorological instrumentation be uniform and complete for all stations. There is one full-time meteorologist assigned to the epidemiologic program. He works with both the epidemiologists and CHAMP personnel to assure that the appropriate and uniform meteorological measurements are made. Because of the reduction in the number of epidemiologic studies since the termination of CHESS field studies, the meteorological support to this activity is now at the proper level. Additional meteorological support will be seriously considered if the number of epidemiologic studies is significantly increased.

Recommendation 10(b) directs that instruments and protocols used in CHAMP be verified to ensure reliable data. EPA is testing all instruments in present use for precision and accuracy. The present system of continuous air monitors appears to have a precision and accuracy such that errors are less than plus or minus 15 percent. Third generation instruments are being evaluated when obtained to improve the present system.

Recommendation 9 pollutant characterization

Recommendation 9 directs that the EPA Health Effects program as well as interagency utilization of all available Federal and extramural resources in the health effects area should be examined with the objective of significantly accelerating research in pollutant characterization. Liaison is maintained with other Federal agencies and the non-Federal sector regarding air pollution characterization. In accord with the 1977 Clean Air Act Amendments, EPA has organized an interagency task force to determine the effects of environmental pollutants on cancer, heart, lung, and other chronic diseases (Ref. 19). In addition, on a case by case basis we are examining the proper balance between pollutant characterization and health effects research. Adjustments are being made as deemed appropriate. We fully appreciate, for example, the necessity of having adequate pollutant characterization data prior to the beginning of laboratory toxicologic experiments. The same principle clearly applies to epidemiologic research.

Recommendations 10(a), 10(c), 12(a) and 12(d)—peer review

Recommendations 10(a), 10(c), 12(a) and 12(d) concern peer review. Recommendation 12(d) concerns expanding the Science Advisory Board charter. The charter has been modified in accord with the Environmental Research, Development, and Demonstration Act of 1978 (Ref. 20). Under the previous and new charter, the Board is authorized to conduct peer reviews. The Board, an independent advisory body, decides how it will respond to requests for assistance. The Office of Research and Development encourages the Board to conduct such reviews. However, it is impossible for the Board to review all research programs because of the limited time Board members can devote to EPA activities. The Office of Research and Development has started discussions with the Board to establish a more effective internal peer review process.

Recommendation 10(a) states that a truly interdisciplinary task force led by an eminent scientist should draw up a program plan for EPA to develop a solid base for knowledge and procedures in aerometric instrumentation and measurements, meteorology, field data gathering, quality control, epidemiology project design and testing, and panel planning. This recommendation will be discussed with the Board. The activities of several groups are pertinent to the recommendation. The Board's Subcommittee on Epidemiological Studies provides advice and assistance in the review and evaluation of proposed or existing programs of epidemiologic studies relating to the health effects of environmental pollutants (Ref. 13). Interactions between our scientists and this subcommittee are continuing. The Environmental Measurements Advisory Committee has visited several EPA laboratories and evaluated current analytical methods and instrumentation research (Ref. 21).

Recommendation 10(c) directs that EPA should have epidemiological questionnaires and panel selection criteria approved by peer groups before the next round of investigations. Specific questions that must be resolved are identified. Regarding the latter, all questions are presently being addressed either by the in-house staff or through contracts. As mentioned previously, the matter of peer reviews is being discussed with the Board.

Recommendation 12(a) directs EPA to establish authoritative peer review panels to assist in improving research coordination. This is being discussed with the Board.

Recommendation 10(d)—ideas

Recommendation 10(d) instructs that EPA should review several ideas raised in the investigation team interviews. These have been reviewed and some have been incorporated into the epidemiology program.

Recommendation 11 reorganizations

Recommendation 11 states that no significant reorganization should occur at Research Triangle Park's Environmental Research Center until the end of Fiscal Year 1977. No significant reorganizations have occurred during that specified time period.

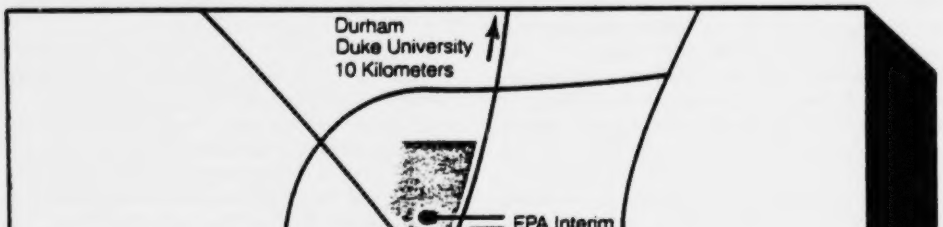
Recommendation 12(b) management

Recommendation 12(b) instructs that EPA should have a stronger focus on management at the Environmental Research Center, Research Triangle Park, North Carolina. In its laboratory reorganization, the Office of Research and Development established a line structure with accountable managers directing the research programs at each laboratory. In turn, each laboratory has programs assigned on the basis of scientific areas that are carried out by its complement of scientists and engineers. In addition to the line management of each laboratory, the Research Triangle Park includes an office of the senior research and development official. Essentially, this official (who is also a Laboratory director) is responsible to the Assistant Administrator for Research and Development to assure effective operation and administration in the laboratories.

Recommendation 12(c) systems analysis

Recommendation 12(c) instructs that EPA should create a systems analysis-operations research program review group. Using sys-

Federal Health Facilities in Research Triangle Park, North Carolina


Durham
Duke University
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Facilities
Chapel Hill
University of
North Carolina
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National Institute
for Environmental
Health Sciences
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National
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Health Sciences
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Federal Site
Raleigh
North Carolina
State University
20 Kilometers

tems analysis and operations research as tools, significant program reviews are carried out by the Office of Planning and Management in its Program Evaluation Division. As needed, the Division:

- —Assembles and evaluates scientific, technological, cost, benefits, and institutional data to critique existing program activities, and recommends alternatives.
- —Develops a long-range policy framework for EPA goals and objectives in consultation with other Agency offices; identifies strategies for accomplishing these goals; and assures that program activities are evaluated in relation to such strategies.
- —Conducts and coordinates analyses and evaluations of Agency-wide programs, including those crossing EPA organizational lines.

Recommendation 13 technical exchange

Recommendation 13 relates to the EPA research program and maximal technical exchange. Recommendation 13(a) directs that EPA should seek cooperative research programs with universities and other laboratories and agencies. The research program in EPA has a large extramural component involving research grants with universities and interagency agreements with other Federal organizations. For example, the overall coordination and detailed planning of the Interagency Energy/Environment Program is the responsibility of the EPA (Ref. 22). Research and development activities under this program are performed by several agencies in addition to EPA. Also, most of the EPA research laboratories are located on university campuses, or in research parks developed by universities, and have close working relationships with nearby institutions. Recommendation 13(b) directs that EPA should promote the exchange of scientists both within and outside the Agency. Over the last few years, the Office of Research and Development has used the Intergovernmental Personnel Act mobility program. This program authorizes the temporary exchange of career employees between the Federal Government and state and local governments, institutions of higher education, and Indian tribal governments. Currently, 66 individuals are participating in the Office's mobility program.

Recommendations 13(c) and (d) concern EPA of funding individual Ph.D. thesis research and the Science Advisory Board development of outreach programs. The Office of Research and Development will discuss these recommendations with the Science Advisory Board and specifically seek their assistance in developing effective outreach programs. Board members have provided general comments but have not yet undertaken any formal actions related to outreach programs.

Recommendations 14 and 17 research role

Recommendations 14 and 17 state that the EPA Administrator should clarify the role of the Office of Research and Development and determine if research should be conducted in its present organizational configuration. EPA is preparing a report to the Congress on planning and management of the Agency's research and development activities. This report will address the most appropriate means of assuring, on a continuing basis, that research in the Agency reflects the needs and priorities of the regulatory program.

Recommendation 15—facilities

Recommendation 15 directs EPA to resolve the separation of facilities at Research Triangle Park. This is the largest EPA field facility and is located in North Carolina within the geographical triangle bounded by the North Carolina cities of Raleigh, Durham, and Chapel Hill. In this area, three major EPA components with a total of 1,857 employees and contractors occupy leased space in nine buildings. In 1967, a 509-acre tract at the Park was donated to the Federal Government for the construction of the National Environmental Health Science Center. An overall master site plan was completed in 1971 and EPA was assigned a 44-acre site for construction of a permanent facility (Ref. 23). Recently EPA developed a long-range space plan for its activities in the area (Ref. 24). This plan is presently under consideration.

Recommendation 16 career development

Recommendation 16 states that EPA management should develop, implement, and defend a professional career development program for each professional. It is the policy of EPA to plan and provide for the training, development, and necessary career planning for employees (Ref. 25). In July 1977, the Agency strengthened existing mechanisms to insure adequate career development (Ref. 26). As part of their annual performance evaluation, supervisors are required to develop a yearly training plan for each employee.

Resolution of Investigative Report Recommendations

Number	Summary of Recommendations	Action
3(a)	EPA should publish an announcement regarding the limitations of the CHESS Monograph.	Shall be implemented
3(b)	EPA should not use the CHESS Monograph without explicit qualification.	Shall be implemented
3(c)	EPA should publish an addendum to the CHESS Monograph including most of the Investigative Report.	Shall be implemented
4(a)	Legislation should be reexamined regarding unrealistic procedures and schedules.	Implemented
4(b)	EPA should design research to gain information and not support positions.	Implemented
4(c)	OMB should allow all necessary resources if public policy requires expeditious research.	Implemented
4(d)	EPA should advise Congress if budgetary restrictions will impact completion of major projects.	Implemented
5	OMB should be asked to develop procedures for prompt review of questionnaire.	Implemented
6(a)	CHESS date analyses should be carried out only on data with high validity potential.	Implemented
6(b)	EPA should publish research in refereed journals in a timely fashion.	Implemented
6(c)	EPA should not publish large projects solely in monograph form.	Implemented
6(d)	EPA should not initiate projects for policy consideration unless they can be completed in a realistic time frame.	Implemented
7(a)	EPA should strengthen the CHAMP aerometric and quality control programs.	Implemented
7(b)	EPA should shorten the time between data acquisition and quality assurance analysis of data.	Implemented
7(c)	EPA should stop employing development stage instruments before qualification testing.	Implemented
7(d)	EPA should not use laboratory models of instruments in the field until they have been field checked and operating personnel trained.	Implemented
7(e)	EPA should reevaluate the opening of the CHAMP operations contract to competition.	Implemented
7(f)	EPA research and monitoring personnel should closely coordinate regarding chemical species.	Implemented
8	EPA should have additional meteorological support for air pollution health effects research studies	Implemented

Number	Summary of Recommendations	Action
9	EPA should examine accelerating research in pollutant characterization.	Implemented
10(a)	An interdisciplinary task force should draw up an integrated air epidemiology-exposure assessment program plan for EPA.	Under consideration
10(b)	CHAMP should verify instruments and protocols so that reliable data can be achieved.	Implemented
10(c)	EPA should have epidemiological questionnaires and panel selection criteria approved by peer groups.	Under consideration
10(d)	EPA should review research concepts obtained from team interviews.	Implemented
11	The Environmental Research Center at Research Triangle Park (RTP) should not be reorganized until the end of FY 77.	Implemented
12(a)	EPA should establish authoritative peer review panels to assist in improving research coordination.	Under consideration
12(b)	EPA should have a stronger focus on management at the Environmental Research Center, RTP.	Implemented
12(c)	EPA should create a systems analysis-operations research program review group.	Implemented
12(d)	The Science Advisory Board's charter should be expanded.	Implemented
13(a)	EPA should seek cooperative research programs with universities and other laboratories and agencies.	Implemented
13(b)	EPA should promote the exchange of scientists within and outside the Agency.	Implemented
13(c)	EPA should fund individual Ph.D. thesis research.	Under consideration
13(d)	The Science Advisory Board should develop outreach programs.	Under consideration
14	The Administrator should clarify the role of the Office of Research and Development and its laboratories.	Shall be implemented
15	EPA should resolve the separation of facilities at RTP.	Under consideration
16	EPA should develop a professional career development program for each professional employee.	Implemented
17	The Administration should determine if EPA should conduct research under its present organizational configuration.	Shall be implemented

Part 3

Report to Congress in February 1979, as required by Section 8(d) of ERDDAA.

Report of the Health Effects Research Review Group

U.S. Environmental Protection Agency
Science Advisory Board
February 1979

EPA NOTICE

This report has been written as a part of the activities of the Agency's Science Advisory Board, a public advisory group providing extramural scientific information to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency, and hence its contents do not necessarily represent the views and policies of the Environmental Protection Agency.

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I. INTRODUCTION

The Congress required an evaluation of the health effects research efforts of the U.S. Environmental Protection Agency in section 8(d) of Public Law 95-155, enacted November 8, 1977.*

Subsequent to the passage of the Act, EPA's Science Advisory Board formed a special committee to perform the mandated evaluation. This Committee, named the Health Effects Research Review Group (HERRG) and composed of experienced scientists and research managers, began their task in May 1978.

The Act stated that the evaluation include the following:

1) The health effects research authorized by this Act and other laws;
2) The procedures generally used in the conduct of such research;
3) The internal and external reporting of the results of such research;
4) The review procedures for such research and results;
5) The procedures by which such results are used in internal and external recommendations on policy, regulations, and legislation; and
6) The findings and recommendations of the report to the House Committee on Science and Technology entitled "The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report."

The Act further stated that

> "the review shall focus special attention on the procedural safegards required to preserve the scientific integrity of such research and to insure reporting and use of the results of such research in subsequent recommendations. The report shall include specific recommendations on the results of the review to ensure scientific integrity throughout the Agency's health effects research, review, reporting, and recommendation process."

The word "research" takes on a broad meaning in a regulatory agency. For the purpose of this evaluation, health effects research will be defined as requested by Mr. Costle in his letter of June 17, 1978, to the Chairman of the Science Advisory Board. A quotation from that letter follows.

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*Section 8(d) of this Act requires that a special evaluation of EPA's health effects research be prepared by the Science Advisory Board (SAB) and the report be submitted to the Administrator, the President and the Congress.

> "To delineate the Congress' charge more sharply, I urge the Study Group to define health effects research to include all planned activities, collection and analyses of data done within the Agency for the purpose of adding to the scientific basis for understanding the effects of environmental factors on human health. This definition would include those activities within the Agency which may be used to assess human risk, and which support standard setting and regulatory decision and any activity which gathers new knowledge about human health, or improves our understanding of human health either directly or which can be used to extrapolate to human health impacts."

In view of the limited time available to the Committee, this study focused on the collection and analysis of data primarily to add new knowledge. The analysis of existing information and data, which already satisfies generally acceptable criteria for scientific adequacy, was not considered to be within the scope of the charge to the Committee. Some requested data were unavailable or not provided to the Committee, therefore,the evaluation is not as complete as initially anticipated or desired.

II. SUMMARY AND RECOMMENDATIONS

A. Summary

The purpose of this report is to summarize the nature of health effects research in a regulatory agency, to describe the current status of that function in EPA, and to present conclusions and recommendations. Supporting data and reports relating to individual ORD facilities are available but are not included.

The Committee visited (either as a full or partial committee) all EPA laboratories performing health effects research. Interviews were conducted with senior laboratory staff, managers, and bench scientists as well as with senior managers in the Office of Research and Development (ORD) and in the Program Offices. For the purposes of this report, a "Program Office" refers mainly to the Offices of Water and Waste Management; Air, Noise, and Radiation; and Toxic Substances, as these are the offices responsible for developing regulations and setting standards or tolerances in response to specific legislative acts. A list of the facilities visited, Committee members visiting each facility, and those EPA employees interviewed or providing information can be found in Appendices C and D.

The Committee also utilized the services of SAB members, other scientists, and research managers on an ad hoc basis (Appendix B).

Programs and facilities were evaluated using a number of criteria relating to the objectives of the research and the quality of facilities, staff and results. Among these criteria were responsiveness of the research function, research influence in the decision making process, coherence of planning and goal-setting between ORD and the Program Offices, and quality assurance through peer review and publications.

The Committee interviewed many competent and dedicated people with a real desire to work in a more effective, efficient and involved way.

Research and development in a regulatory agency is a complex task, one requiring research targeted to regulatory requirements usually having short (six month to two year) time frames. Research and development must be related to specific regulatory needs. Identification of gaps in data and needed research effort necessitates cooperative planning between program managers*, often unfamiliar with research, and research managers, who are often insensitive to regulatory pressures and requirements. Researchers, as professionals, may have difficulty in identifying results which will satisfy regulatory needs when these results are not in their scientific specialties. Constantly altering budgetary allocations to adapt to rapidly changing regulatory needs aggravates research-program staff relations. For these and other reasons, ORD has frequently been viewed as unresponsive by many program managers, who do not, in general, depend upon ORD to support their regulatory efforts. The Committee concluded that it would require far greater joint planning and coordination of ORD and Program Office staffs if ORD outputs, useful to regulation, were to be commensurate with the funds allocated. At present, it is not an effective or an efficient system. The dilemma of research in a regulatory agency is further treated in Chapter IV.

The most successful and useful research programs were found where there was a close working relationship and understanding between scientists in the laboratories and their counterparts in the Program Offices. Such communications are essential to an understanding of priorities, quality demands, timing and what was truly needed to back up the regulatory process in the short and long terms. Poor results were seen all too often, however, because close relationships did not exist.

Pilot research committees have helped to establish essential communications between those who have direct and indirect responsibilities. Where successful, the resulting agreements, e.g., Drinking Water and Pesticides, have helped to make research more responsive and have cut across jurisdictional barriers to establish objectives, goals and plans. The pilot research committees are one means to an end, but shorter and more direct communications lines are needed between data generators and data users.

Beyond a committee approach, there seemed to be little consideration of organizational structures designed to streamline decision making. Hopelessness was expressed many times by those concerned when faced with the seemingly obdurate character of the civil service system and the highly placed, inflexible, and sometimes less than adequate individuals who occupy unessential positions. Inflexibility makes it difficult, indeed, to place people properly and to transfer or get rid of people not performing up to expectations in their jobs.

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*A program manager is defined as that person in the Program Office who is responsible for developing the regulatory or standard-setting activity for a specific program as mandated by legislation. A research manager is that person in ORD who is responsible for formulating, planning, and executing specific research programs.

Recent changes in the civil service laws were not seen as adequate to effect much improvement. Desirable changes can occur, but they will require enormous effort, training in, and application of the principles of management by objective and job performance evaluation to establish a clear understanding of what is expected of each employee.

B. Recommendations

The Committee recommends that:

> (1) ORD and Program Office leadership take immediate steps to coordinate all research planning and activities in the Agency. Joint planning to identify information needs must begin as soon as a decision is reached to prepare a regulatory proposal.

Immediately following a program decision to develop a regulatory proposal, Program Office and ORD staff should be assigned to review existing information needs. This group should be given authority to organize Program Office-ORD staff to identify regulatory needs for specific proposals and outline the required research to fill the gaps.

> (2) ORD continue to use appropriate research committees, but they should not be ORD's exclusive planning mechanism.

Research committees, initiated on a pilot scale in 1978 to help ORD plan and coordinate its research activities with the Program Offices, should be used sparingly. These research committees, really task forces, will be most useful when research needs relate to multiple Program Offices and laboratories.

The research committees should be used for identification and prioritization of needs. These committees should not be involved with research implementation.

Key managers within ORD should devise mechanisms to develop well understood objectives, goals, plans and measures of performance for how research should be conducted.

The Committee does not believe that it will be possible for ORD to fulfill its function without extensive agreement by key personnel on objectives, goals, plans, and measures of performance. It might be helpful for ORD to hire experienced management specialists, as consultants, to help address some of the difficult managerial problems which currently exist.

ORD leadership must take steps as soon as possible to work out an understanding with Assistant Administrators in the Program Offices to simplify and shorten lines of communication and to cut to a minimum the reprocessing of decisions by the Washington ORD staff.

> (3) The scientific staff of ORD identify subject areas and establish active investigatory groups to pursue long term research essential to regulatory needs. (Implementation of recommendation 1 will ensure that long term research efforts remain relevant.)

There should be a long-term ORD investment in researchers and facilities to develop highly active and productive groups in those research areas which are central to large segments of the Agency's regulatory activity. Allocation of a specific percentage, at least 10%, of the ORD budget for relevant research in case subject areas seems to be reasonable.

> (4) The incorporation of ORD research results into criteria, standards, and regulations be strengthened.

ORD must stress, at all levels, the importance of producing results and assisting with their incorporation into regulations and standards. ORD has neither fully recognized or accepted this criterion for judging its efficiency, nor developed mechanisms for efficient utilization of research results by Program Offices. ORD does not maintain records of results which have been incorporated into regulations.

The formation of the Environmental Assessment Groups is a step in the right direction. Part of the responsibility of these groups should be the documenting of which research results have been utilized, the continuing audit of the usefulness of ORD results to regulations and standard setting, and getting feedback from the Program Offices about the research and research planning activities. The Committee found the model, outlined on page 9 of Volume III of "Research and Development in the Environmental Protection Agency," to be still relevant for Agency use.

> (5) Responsibility and authority for implementation of research and reporting of research be vested in the laboratory directors and the staff scientists, after agreement on research plans.

The Committee feels that too many specific directions regarding research implementation come from headquarters. This prevents the scientists from using their talents and diminishes the scientific climate for innovative research.

> (6) After agreement on responsibilities for research implementation, laboratory directors and their scientific staff be permitted to performed their assigned tasks. (See recommendation 5.)

Laboratory staff need protection against unwarranted mandates, incursions into allotted time for research, and reorganizations and spurious changes in policies that occur with the all-too-frequent changes in leadership. The scientists also need a sense of the Agency's long range commitment to its stated goals.

> (7) An expansion of the Interagency Regulatory Group (IRLG) activities be carried out. The excellent planning initiatives of IRLG should be extended to include environmental health research.

The IRLG is seen as an excellent beginning with the potential of reducing duplication and confusion among agencies. This effort should be extended to strengthen coordination of research planning by all agencies conducting environmental health research.

> (8) A simple, easily understood accounting system be established for planning, assigning and monitoring use of funds and personnel relative to ORD's intramural and extramural programs.

Effective use of limited funds and personnel requires that they be carefully managed. The accounting systems now in use are inadequate. At the present time, analyses are not performed to place in perspective salaries, equipment costs, services, etc. Those cost breakdowns are necessary to give ORD information about responsive and nonresponsive work at the different laboratories performing health effects research.

> (9) Standard procedures for awarding contracts, grants, and cooperative agreements, and monitoring extramural research be simplified and enforced.

Current elaborate rules for contract and grant awards should be reviewed and revised to promote efficiency and timeliness of extramural awards. All personnel must adhere to these new procedures. This would end the current abuses of the extramural award system. Procedures should be adopted to ensure adherence to the new requirements after revisions are made.

The monitoring procedures should indicate methods for evaluating the performance of contractors and grantees during and after completion of their work. Furthermore, the extramural research results should be published in peer reviewed scientific journals. EPA-published reports are no substitute for open literature publications.

Adequate travel funds should be allocated for proper site visits and for monitoring of extramural work. Presently, there is no routine, operational audit of the quality of extramural research.

Responsibility for extramural research (planning, awards, and monitoring) should be made according to the staff's capabilities to effectively plan and monitor such research. This should take into account the amount of independent in-house research expected from the staff scientists. Extramural monitoring assignments should only be made to scientists who have demonstrated professional competence and are thoroughly familiar with how research is conducted in the field being monitored.

> (10) Scientific peer review of proposals, programs, and intramural and extramural research be greatly intensified.

Scientific credibility and defensibility of research done in support of regulations are key elements of the success and acceptance of the Agency's role by the public. The Committee feels that, to the maximum extent practical, scientific peer review mechanisms should be utilized to improve the quality of final research results.

All programs and organizational units should be periodically subjected to peer review by qualified scientists from outside the Agency. All proposals and completed research should be reviewed by peer scientists within the Agency, and representative items should be reviewed by scientists outside the Agency.

The quality of research in EPA is important not only because any research should meet standards acceptable to the scientific community but also for reasons derived from the regulatory nature of the Agency.

To ensure acceptability of research results, the studies must be reviewed by one's scientific peers and published in reputable scientific journals. Failure to so treat results of research investigations involves the risk that review will occur at a later date, in a adversary situation, with possible refutation of results and embarrassment to the Agency.

> (11) A dual-ladder promotional system be implemented for qualified scientists to advance in grade and salary without having to undertake supervisory or managerial responsibilities.

Presently EPA has a promotion ladder inadequate to allow scientists to remain in the laboratory and be promoted strictly on the basis of their scientific excellence. EPA suffers from a poor reputation as far as the scientific quality of its health effects research is concerned. This reputation is not totally deserved. There does need to be a system whereby both qualified scientists and qualified managers can each advance and be rewarded in their own fields.

Well qualified personnel are the key ingredient to the conduct of a scientifically sound research program. At the present time, there are both formal and informal procedures that encourage scientists seeking promotions to accept supervisory and administrative responsibilities, thereby reducing the amount of time they have to spend on laboratory research.

When personnel are assigned to senior management positions, primary consideration should be given to individuals who have demonstrated scientific and managerial capabilities; an understanding of how research is planned, conducted and reported; and the ability to communicate research information and needs to both scientists and non-scientists.

> (12) Research management give immediate attention to instituting, in the laboratories, a variety of procedures to create an atmosphere conducive to scientific excellence.

Even though the laboratories are located on or near university campuses or other research institutions, EPA scientists were somewhat outside the mainstream of scientific events. The Committee, therefore, urges management to regularly schedule seminars in which both outside scientists and Agency scientists participate, invite outside scientists to spend time in EPA laboratories (in addition to use of the Interagency Personnel Agreement--IPAs), encourage EPA scientists to spend time in outside laboratories (an exchange program), sponsor workshops and symposia, and generally institute a closer interaction with geographically close institutions.

(13) ORD and senior Program Office staff rotate assignments, preferably on the basis of those ORD and Progam organizational units which consistently interact.

It is essential for effective performance that Program Office and ORD managers understand the problems and capabilities in each organization. Program managers are often unfamiliar with research planning, laboratory work and the inherent time constraints. Likewise, research managers are often unaware and insensitive to regulatory pressures and requirements and with the dilemma of how to present data in a form useful to the Programs.

(14) The research program using the clinical inhalation exposure facility at Chapel Hill, North Carolina, be fully staffed and a sound research program implemented as soon as possible.

The clinical inhalation facility at Chapel Hill is a unique facility, engineered to deliver the desired exposure levels; however, the scientific program, staffing, and plans to utilize the facility are totally inadequate--a very conspicuous waste, as it now stands.

ORD should immediately assess the future need for and use of this facility, establish goals and support for the facility, and assure that the facility is not wasted--even if EPA has to make it available to outside groups. This facility was designed for long range studies to accurately assess and predict the potential adverse effects of selected environmental chemical agents.

The inhalation program, once developed, should be scientifically peer reviewed and approved.

III. COMMITTEE MEMBERSHIP, APPROACHES AND PROCEDURES

A. Committee Membership

The Health Effects Research Review Group (HERRG) consisted of core members and consultants selected for their scientific expertise and research management skills. The consultants supplemented core members and were used to provide specific expertise for the evaluation of individual laboratory programs or special topics of research. A list of Committee members and consultants is Appendix B.

B. Approach to the Assessment of R&D and Procedures Used

It was apparent from the outset that the Committee needed a clear understanding of the mission of health effects research as seen from the viewpoints of the personnel in both the various Program Offices and ORD. Responsiveness of the research function to the pressing (often mandated) needs of the Program Offices has been inadequate in the past; this problem has been clearly described in a report by a committee of the National Academy of Sciences, *Analytical Studies of the U.S. Environmental Protection Agency*, *Volume III*: "Research and Development in the Environmental Protection Agency," 1977.

Of necessity, the Committee had to subdivide much of its investigation into small study group activities. A common approach was taken to make it easier to analyze and assemble the findings of the various study groups into an integrated final report. Thus, the research function of the Agency was to be analysed *in the context of the regulatory responsibilities of the Agency*, which in turn requires a reliable and defensible data base for decision making. The Committee agreed that research can only be understood if the reciprocal relationship between the users of the information (the Program Offices) and the generators of the information (ORD) was examined. The perceptions of both the generators and the users were, therefore, to be probed to determine if there were *shared* goals and a *shared* understanding of what is known, what is unknown, and what needs to be known. It was also necessary to determine whether there was a *shared* understanding of the time frame necessary to generate or assemble the needed data. These perceptions were to be examined at several hierarchical levels to determine if the intentions of the supervisors were accepted in a way that motivated the respective organizational units regardless of location or attitudinal preferences.

While conducting interviews and fact-finding sessions, Committee members tried to use some of the following checkpoints as they were appropriate for the various situa-tions. These points were the basis for the formulation of this report.

a. Checkpoints relating to the mission of health-related research as it supports short-term and long-term Agency needs:

1. Responsiveness of the research function (as defined at the outset)
2. Sense of urgency and commitment of the research function
3. Research influence on judgments made on the decision making process (level of influence and dependence by the program offices)
4. Coherence of planning and goal setting between the Program Offices and ORD (Are budgets really reconciled and supported by both the Program Offices and ORD?)
5. Examples of good and poor responses by ORD
6. How and by whom is the decision made to initiate and conduct specific research investigations?
7. How are information gaps identified? How are long-term trends with potential environmental impacts identified? How are long-term research needs defined and planned to assure budgetary support?
8. Beyond the Program Offices and the ORD functional organizations, what other factors help influence what research is to be done?

b. Checkpoints relating to the quality of health effects research as it supports short-term and long-term Agency needs:

1. Quality assurance:
    a) Good laboratory practices
    b) How is quality assurance implemented to improve the defensibility of results?
    c) Evidence of attention to detail and carefulness (facilities, work flow, housekeeping, attitude, safety program)
    d) Personal scientific integrity, including quality of planning and experimental design, rigor of analysis, courage to disprove one's hypotheses (or hypotheses of a superior), and acceptance of opinions of qualified peers
    e) Can the most qualified people be quickly identified?
    f) Is the civil service system seen as a positive factor in the encouragement of a good research program within EPA?

2. Publication of results (reporting)
    a) In journals requiring scientific peer review, internal government publications, journals or meetings not requiring scientific peer review
    b) Methods for approving manuscripts before release or publication
    c) Is publication seen as helpful to career development?

With these checkpoints in mind, the Committee conducted its assessment through a series of fact-finding sessions and public meetings in Washington and in various EPA laboratories (see Appendix C). The Committee chairman and co-chairman first discussed the charge and the plans for accomplishing the evaluation with the appropriate Congressmen and their staffs. Subsequently, the Committee met with the Administrator, the Assistant Administrators and other senior EPA policy and management staff in various Program Offices, and with representatives from the regions, laboratory directors, senior science managers, and individual laboratory scientists (Appendix D). The Committee members reviewed legislative mandates, various EPA documents, and other papers and memoranda relating to the Committee's charge.

IV. RESEARCH IN A REGULATORY AGENCY: THE CONFLICT DEFINED

A. Present and Future Agency Needs for Data

Volumes have been written on regulatory agency research needs in general and on EPA research needs in particular. Therefore, the Committee approached the subject of the research and development needs of EPA with trepidation and elected initially to describe the pressures and constraints imposed generally upon a research and development group in a regulatory agency and those imposed upon EPA in particular.

Program administrators in regulatory agencies are captives of the calendar deadlines imposed for regulation by the specific statutes they enforce. These agencies routinely deal with Congress, irate constituents, citizen groups, the media, and others. The professional skills which contribute to their success and/or survival are all devoted to integrating immediate pressures and existing knowledge into a set of regulations acceptable to all. This is a difficult situation, one requiring sensitivity to human behavior and appreciation for the relevant available data base. Regulations are usually compromises, their political socio-economic impact and whether they can be enforced. The scientific and technical bases for a regulation will be put to rigorous test if, and only if, the regulation is challenged. Judicial review will incorporate and consider all relevant data; an administrative "gamble" made in the absence of sufficient data to support regulation will very likely lead to remanding the rule to the Agency. Development, promulgation and enforcement of regulations, particularly in an area as underdeveloped and evolutionary as environment, is a difficult exercise.

The formal challenges to regulation are cyclical. Because of inflationary pressures on regulatees since 1976, there has been an increasing trend toward challenging environmental regulatory promulgations. The courts have been sympathetic to the innovative promulgations of EPA, but the economic impacts of EPA administrative interpretations of enabling statutes have led to regulatee demands for more complete substantiating data for promulgated rules; those demands will increase in the future. Even those sympathetic to prudent Federal environmental regulations are demanding higher standards of proof during this highly inflationary period of increasingly demanding and varied Federal regulation. Because environmental rules are still perceived by many as a luxury affordable only by a prosperous private sector, EPA must anticipate continuous, more sophisticated private sector challenges because of inflationary pressures.

These challenges will be overcome only by convincing arguments for regulation, arguments drawing upon defensible data. These data will have to relate specifically to improvements in human health if EPA is to fulfill its mandate as an Agency. In the future EPA will increasingly have to document health gains anticipated from allocation and expenditure of large sums of money for regulation and control of environmental pollution.

B. Investigatory Time Frames

Specific statutes include timetables for regulation assigned by Congress. The Agency has formulated a table of regulations scheduled or in progress (Appendix E). Program administrators will formulate these regulations with whatever data are available prior to and until the scheduled completion date. In general, schedules for EPA to write regulations are short; 6-12 months is normal, while 18 months is considered long. These are short time frames for generation of new information in the laboratory or in the field. EPA Research and Development Office (ORD) personnel have had enormous difficulty responding within the time allotted. It is essential that ORD and Program Office personnel carefully evaluate information needs critical to implementation of scheduled regulations. This must be done as soon as a statute is assigned to EPA for enforcement. In this way, ORD will be able to utilize the maximum available time to generate needed data for regulation. We did not perceive that research needs are routinely approached in this manner.

C. Investigator and Program Staff Interactions

The perceived needs of program managers are usually very specific and often conflict with needs perceived by researchers. For example, researchers may regard experiments requiring toxicity data from animal exposure to pollutant agents at concentrations far in excess of those likely to occur under normal exposure as of little relevance to scientific understanding. Program personnel, however, may regard demonstrated toxicity data, even at unrealistically high exposure levels, as a rationale for regulation. Sorting out these differing perceptions requires personal interchange if ORD is to respond in a timely and meaningful manner. Too often in the past the Program Offices have perceived ORD as unresponsive because results were of a kind different from what had been anticipated and because research time frames were too long to allow the Program Offices to use the data produced. Under these circumstances, program administrators did not look to ORD for solutions to their problems.

Principal Program Office and ORD administrators are located in Washington, D.C. ORD investigators are located in laboratory facilities throughout the nation. Specific administrative mechanisms are required to ensure that communications occur between Program Office administrators and ORD investigators as research in support of specific regulations progresses. In 1978 five research committees were initiated on a pilot basis to help ORD plan and coordinate its research activities and become more responsive to the needs of designated Program Offices. These pilot research committees have helped to provide an essential communication function; furthermore, they have helped to establish understanding and commitment to objectives, goals, and plans. Carefully selected research committees are seen as a means to an end, although a cumbersome one, because their meetings help to educate those who need to know. In the long run, however, the functions served by the pilot research committees need to be institutionalized so that laboratory directors are not excluded from key roles in leadership or from maintaining a high level of competence in their respective laboratories.

Program administrators frequently have their primary training in the legal or engineering professions; they are often not familiar with the state-of-the-art of ORD scientific research. ORD utilizes scientifically trained personnel at all levels of the organization, those working at science on a daily basis. One can draw flow diagrams of the decision making processes in a regulatory agency, diagrams illustrating ORD and Program Office personnel interactions. However, in the final analysis, exchange of information and resolution of issues is required of persons with essentially different bases of understanding. There will be a major built-in obstacle to communications between ORD and Programs Offices as long as ORD relies entirely on scientific managers and the Program Offices on managers who pride themselves on their pragmatic approach, managers grounded in law and/or engineering sciences. By one mechanism or another (rotation of assignments, creation of new positions for complementary professionals in each Program Office and ORD), there must be promotion of ORD-Program Office communication by ensuring that senior managers have a common language(s).

D. Evaluating the Responsiveness of ORD

The responsiveness of ORD is judged by a variety of groups and individuals, including EPA program managers, Congress, citizen groups, and the media, to name a few. The Committee probed primarily EPA program managers' perceptions of ORD's responsiveness to their needs. Senior program managers have indicated that there have been recent improvements, but much remains to be done. In the past, many Program Offices did not participate in ORD planning. Recent joint ORD-Program Office research planning exercises, such as the pilot research committees, have caused Program Offices to be more favorably disposed toward ORD activities.

Ultimately, ORD's response to the Program Offices will be more stringently judged by how effectively the research results meet the specific needs of the regulators in a timely and scientifically rigorous fashion. The current auspicious climate for ORD pilot research committee planning must not be confused with future ORD outputs necessary to satisfy hard-pressed Agency program managers. For this reason, the major ingredients of ORD research that would allow ORD to be considered "responsive" to regulatory program needs will be briefly discussed. Following this discussion will be comments on the current EPA research process from the planning stages to the final utilization of results by Agency Program Office staffs.

The timing of the delivery of research results to a Program Office is a major factor contributing to the perception of ORD's responsiveness to Agency needs. Regardless of the quality of research results, they are viewed as only marginally useful if available after statutory deadlines have passed. One can argue that in the long run "late" results will be integrated into environmental programs, but this does not engender Program Office staff confidence in or support for ORD.

The scientific and technical soundness of ORD results is crucial if EPA Program Offices are to sustain their regulatory positions. Transfer of weak results by ORD will lead either to rejection of these results by administrators or to utilization with subsequent public embarrassment upon disclosure of a weakly supported position and/or reversal of the Agency position by the Courts.

In addition to being scientifically defensible, research results must be targeted to meet Program Office needs. Needs must be commonly perceived and agreed upon by researchers and program administrators. Dictation of needs by regulatory staff to researchers can result in untimely and fruitless investigations; likewise, researchers with inadequate understanding of program needs may pursue scientifically sound studies which are irrelevant to the Programs.

The understanding of ORD results by potential users is probably a major ingredient of the perception of responsiveness. ORD must not only deliver sound results in a timely manner, but must also translate these results into terms and concepts understandable to the users, i.e., the Program Offices. ORD has a responsibility to assist its users in understanding the strengths, weaknesses and full significance of those research results transmitted for Agency use.

The above ingredients of "responsiveness" relate to the research function as it serves regulatory needs. Each ingredient must be carefully developed and nurtured, literally on a project basis, if expectations of ORD efforts are to be fulfilled.

With this brief introduction to the demands placed upon ORD, specific aspects of performance of health effects research and development in the Agency will now be discussed.

E. What is an Investigatory Product in a Regulatory Agency?

The investigatory product in a regulatory agency is that body of scientific information and data base which is either available to or resides with the scientific staff. The product must be provided to the Program Office in a form that is useful, understandable, and defensible in setting reasonable standards and for writing regulations.

This scientific information can be provided to the Program Offices in many ways. The best way would undoubtedly be to have the research described and published in professionally peer reviewed journals, but information can also be provided through monographs, letters and verbal presentations. The key to the desired investigatory product is for the Agency to have an in-house core of capable scientists who understand the regulatory and standard setting requirements, who can perform the necessary literature searches, can perform their own research and evaluation, and can freely attend professional scientific meetings where discussions and information exchanges occur.

V. OBSERVATIONS OF CURRENT EPA RESEARCH AND DEVELOPMENT

A. Identification of Research Needs

ORD can be viewed as a large multifunction apparatus capable of responding in a variety of modes if appropriate planning of the necessary dynamics and a complete "tune-up" occur prior to "start-up." The initial step is to identify the required outputs. ORD outputs should be responsive to regulatory needs, in the short or long term. At present and, indeed, during the entire history of EPA, short term R&D needs have been stressed. We do not see any conflict between simultaneously sustaining research programs with long (years) and short term (months to years) goals, provided Program Office-ORD concurrence is reached as to these goals.

Historically, Program Offices outlined needs according to their perceptions of the problem. It was a hierarchical planning process which gave the scientists at the laboratory little understanding of what was needed or why. Laboratory scientists often communicated with lower level Program Office staff who did not fully understand the needs and priorities of their program.

There seems to be no systematic identification of information gaps (research needs) in the Agency. This identification should take place as soon as EPA receives legislation on which it must act; it requires close cooperation between the appropriate Program Office and ORD scientists, especially those in the laboratories. These staff members should carefully analyze the Act to assess what the Agency must do to gather the needed information and to fulfill the requirements of the Act. Additional research needs come from the process of drafting regulations and from writing the criteria documents when perceived needs for information are recognized. Better identification of needs takes place when there is a close association between ORD and the Program Office, but this must be directed throughout the Agency in a systematic way.

Long-term (anticipatory) research in subject areas central to Agency responsibilities should be planned as a natural extension of the identification of gaps in the data base. It cannot be designed in a vacuum, as an activity to be initiated or terminated at will. When effective cooperation occurs between ORD laboratory and Program Office personnel and when effort is expended to define common objectives, goals, and plans, opportunities are likely to arise for defining relevant, long-term research programs.

The perception of needs for longer term research arises from the interaction of key regulatory people and creative researchers who are in touch with the issues and the scientific literature. People who do research, read scientific literature, attend meetings and work cooperatively with the Program Offices are those with the best resources to define needs. The Committee believes that the stress on identifying long-term research needs must come from ORD and that more attention must be devoted to identifying these needs and pursuing the associated research studies.

The pilot research committees have helped to identify gaps deserving further research effort, to date only short term; but even this has helped to gain better insight into Agency priorities. Because of the large number of people involved, these pilot research committees are cumbersome, but they have forced a meeting of minds among key people in the Program Offices and ORD. In fact, the identification of research needs by individuals with diverse backgrounds and responsibilities is a very strong feature of the pilot research committee effort and should be retained regardless of the ultimate fate of the activities of these committees. This should be expanded to include identification of long term needs.

Several efforts at identifying research gaps and implementing research should be highlighted. The Drinking Water Program has been an example of effective cooperation in identifying and implementing research needs, whereas the Human Inhalation Exposure program at HERL, RTP (Chapel Hill) and the Animal Exposure Program at HERL, Cincinnati are examples of very poor coordination. In the area of pollutant inhalation studies on human subjects, the scientists of the Chapel Hill facility have attempted to implement longer range studies to predict and assess more accurately the potential adverse health effects of selected chemical agents. In general, ORD administrators have been sympathetic to funding short-term inhalation projects, but have not been supportive of longer term inhalation research programs. The Inhalation Toxicology (animal model) Program at HERL, RTP, on the other hand, was enthusiastic about its relationship with the Program Office. This group is well supported, largely as a result of a sustained effort by the section leader to keep close contact with ORD and Program Office personnel in Washington. Development of new methodologies was considered to be a major responsibility of the group working on animal inhalation toxicology; they expressed the desire to be involved in toxic substances support as well. This group also supervised contracts and grants. Management of both grants and contracts in addition to the "in-house" responsibility was seen as a desirable component of the total job done by the Inhalation Toxicology Section. A key element of this program seemed to be the desire on the parts of the Program Office and the laboratory to engage in cooperative planning and goal setting. The result is a very spirited and productive group of researchers.

Scientists in the Diesel Exhaust Program at Center Hill (Cincinnati) clearly foresaw the emerging importance of diesel engines and attempted to start long-range research several years ago. These projects were turned down by ORD staff members in Washington, who have recently recognized the need for such studies. Work is now frantically underway to obtain needed results to meet the statutory deadline for establishment of diesel emissions criteria.

B. Planning Research Projects

1. Budget Formulation

During the period of our Committee review, the Agency was in the second year of zero based budgeting (ZBB), i.e., fiscal years 1979 and 1980 budgets were in progress. Funds are authorized and appropriated directly to ORD in categories related to enabling legislation or special projects.

Prior to the introduction of the ZBB process, senior ORD personnel often established project allocations without communicating with Program Office managers. The zero based budgeting process has been an exasperating (but probably desirable) experience for all concerned--Program Offices, ORD, and laboratories alike. It has forced a certain amount of communication and has led to some good, though tortured, outcomes, especially in the pilot research committees. However, communications are still occurring only between ORD and Program Office personnel of relative seniority. We perceive that many bench scientists in ORD do not understand the relationship of their work to overall ORD and Agency goals. If communication involved the laboratory investigators doing the work, even more effective decisions could be reached, while simultaneously gaining the commitment of the researchers to the work.

An additional budgeting problem is the mismatching of personnel ceilings and funding for specific programs and laboratories. Numerous examples were found in which program areas in specific laboratories had very few or no people assigned and relatively large amounts of funds available. In a few instances, relatively large numbers of personnel were assigned with limited funds available. At the headquarters level, the view was frequently expressed that OMB had minimized management's latitude for shifting personnel between programs to better match program needs and fund allocations. Laboratory personnel expressed a feeling of hopelessness in dealing with the problem and were, on occasion, forced into the unrealistic posture of showing, for the record, programs with substantial funding managed with zero personnel; obviously this does not happen. The people who are assigned to manage the program simply charge their time to some other program that has a more adequate manpower ceiling. The result is manpower accounting by progam that is suspect, at best, and probably of limited value.

Clearly, if laboratory directors are to be effective research managers, they must be given the latitude to utilize assigned personnel without rigid program area constraints. A change in approach should allow laboratory directors to place increased emphasis on developing the appropriate mix of disciplinary skills of their staffs to better serve current and future program needs.

Allocation of travel funds is another budget problem. When travel funds are allocated to the laboratories, consideration should be given not only to the number of scientists in the laboratories, the degree of participation in extra laboratory Washington mandated activities, and the required extramural program monitoring required, but also to the geographic location of the laboratories with respect to these activities and to the location of national scientific meetings. Furthermore, increased flexibility should be given to the laboratory directors for control and utilization of travel funds. For example, the laboratory director at the ERL in Duluth should be authorized to approve travel for his staff to go to Canada. One of the major functions of this laboratory is scientific cooperation with their counterparts in Canada. Yet this collaboration is minimal because travel to the Canadian laboratory in Thunder Bay is considered foreign travel and must be approved each time, well in advance, by ORD headquarters in Washington.

2. Research Program Formulation

The Committee senses that the major contribution of the pilot research committees in program formulation has been to overcome previous inadequacies in planning and to initiate discussions of research by the many individuals with an interest in the outcome and utilization of the work. The previous "old system" of hierarchical planning failed to establish understanding and commitment by those who should have been involved. The pilot research committee approach to planning has been warmly endorsed by laboratory staffs because they, personally, provided inputs and gained familiarity with and perspective of the entire program and an awareness of their projected contributions to the entire program. This type of "grass-roots" motivation must be retained, but the leadership must also be involved in the process. Methods need to be established to institutionalize the involvement and commitment of the staff through proper involvement of laboratory directors, as well. Pilot research committees are a useful means to an end, but they are no substitute for accountable leadership, which must be responsible for the integrity and quality of the final product.

When laboratory personnel did feel that they had an influence in setting priorities, they became involved with input to the Program Offices, became involved in the objective setting, and became involved in the design of protocols to meet objectives. The drinking water projects are outstanding examples and illustrate many of the elements of success that need to be emulated by others. The reputation of the people, their professional standing, and the history of performance stemming from the Cincinnati laboratory and its predecessor, the Taft Center, are influential factors which command the respect and attention of the Program Office. A critical factor in responsive and quality programs is the need to maintain a continuum of qualified, knowledgeable personnel. Also, it is important to recognize that, in the drinking water program office, there are counterparts to ORD staff who understand the scientific and technical issues.

3. Pre-project Evaluation of Productivity and Costs

The laboratories in ORD are mostly media oriented, and scientific program projects and resources are assigned accordingly without assessment of the cost-effectiveness of performing research in each specific laboratory.

ORD, or an outside agency, should perform a yearly assessment of each laboratory's past performance with respect to the quality of the research information produced, the timeliness of delivery of research results, the cost-effectiveness of the laboratory, and other factors which deal with a laboratory's performance and productivity. Only after such assessment has been performed and deficiences corrected should the scientific work (decision units) and resources be assigned to a specific laboratory.

4. Good and Poor Planning

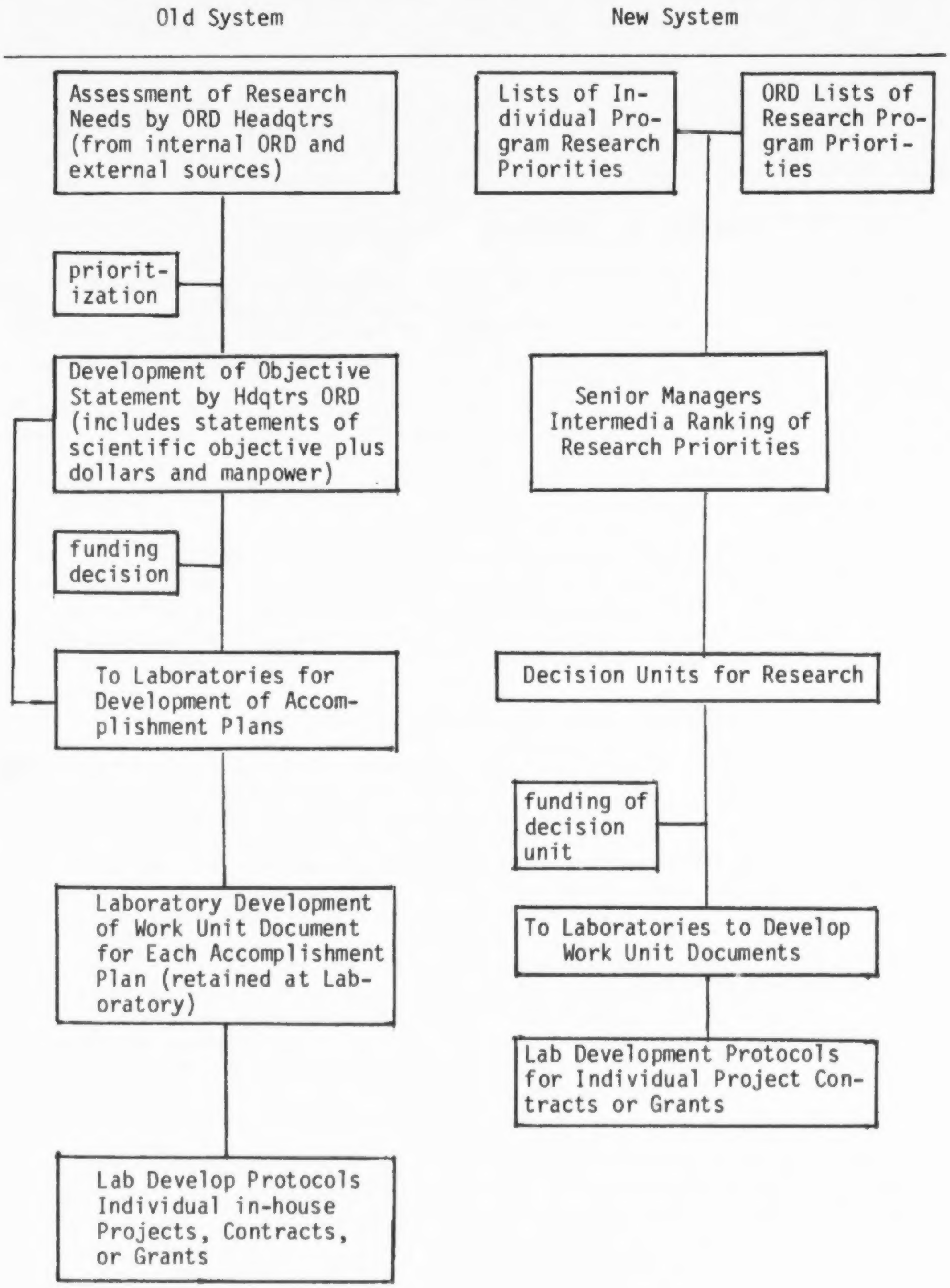
a. Some examples of good responses by ORD

- The drinking water program at Cincinnati
- The animal inhalation toxicology program at RTP
- The pesticide pilot research program involving program and laboratory personnel
- The Wenatchee Laboratory studies of field exposure of applicator to pesticides (relevant work goes back in history and should be better utilized)

These good responses all have a very important common element; namely, the participants work at good communication. Objectives, goals and plans are understood by the affected parties. Solid scientific approaches are being utilized and researchers in the laboratory are involved with personnel in the Program Offices.

Figure

Diagrammatic Representation of Old and New Systems to Develop Experimental Protocols at Bench Level of Investigation


Old System
New System
Assessment of Research Needs by ORD Headqtrs (from internal ORD and external sources)
prioritization
Development of Objective Statement by Hdqtrs ORD (includes statements of scientific objective plus dollars and manpower)
funding decision
To Laboratories for Development of Accomplishment Plans
Laboratory Development of Work Unit Document for Each Accomplishment Plan (retained at Laboratory)
Lab Develop Protocols Individual in-house Projects, Contracts, or Grants
Lists of Individual Program Research Priorities
ORD Lists of Research Program Priorities
Senior Managers Intermedia Ranking of Research Priorities
Decision Units for Research
funding of decision unit
To Laboratories to Develop Work Unit Documents
Lab Development Protocols for Individual Project Contracts or Grants

b. Some examples of poor responses by ORD

The Human Inhalation Facility at Chapel Hill is an unusual facility, engineered to deliver the desired exposure levels, but the scientific program or plan to utilize it is totally inadequate-- a very conspicuous waste.

The Diesel Exhaust Program at Center Hill was prevented from doing adequate dosage response tests because of directives from Washington. The Epidemiology Program associated with the Diesel Emissions Program lacked adequate and mature direction.

C. Performance of Research

EPA's intramural health effects research is conducted in two major laboratories and in portions of three other laboratories, which were established primarily for other purposes. The major laboratories are Research Triangle Park, North Carolina, and Cincinnati, Ohio. Small programs are in effect at the environmental biology laboratories at Duluth, Gulf Breeze, Narragansett, and the Environmental Monitoring and Support Laboratory, Las Vegas. There are also health-related field laboratories in Wenatchee, Washington and W. Kingston, Rhode Island.

All of the laboratories have close relationships with neighboring universities; in some cases the laboratories are located on university campuses (the main Cincinnati Laboratory, the W. Kingston Laboratory, and the Human Inhalation Facility at the University of North Carolina, Chapel Hill).

1. Adequacy of Facilities for Research

The facilities of the health effects laboratories are generally excellent. The major exceptions are the RTP laboratory and the W. Kingston facility, neither of which was built for biomedical research purposes. Some laboratory buildings, on the other hand, were constructed for biomedical research within the past five years (e.g., Cincinnati). In spite of limitations of physical plant, such as the absence of modern animal care facilities at Research Triangle Park, EPA laboratory staff have improvised and created the physical conditions necessary for good research. The laboratories are, in general, notably well-equipped for physical and chemical analysis and modern biologic research; they also appear to have adequate library, data processing and statistical services on the premises or conveniently accessible.

The Committee did not conduct a formal audit of good laboratory practice at any laboratory visited. However, the Committee did consider as part of their general review many of the items that would be considered in such an audit. It was the

Committee's perception that additional attention is needed in this area if EPA laboratories are to achieve the same standards that EPA expects from research conducted outside the Agency and submitted to the Agency.

Some of the specialized physical facilities are unique in the cabability of their chambers to provide accurate concentrations of gasses and aerosols at very low concentrations for human exposure. The inhalation facilities at Cincinnati for experimental animal exposures and the Inhalation Exposure Facility at Chapel Hill for controlled human exposures are good examples.

Housekeeping and safety programs were generally quite satisfactory. Animal facilities in only two laboratories were examined (Cincinnati and RTP). The facilities at Cincinnati have been approved by a national animal facility accreditation committee, while no such accreditation has been attempted at RTP due to its many deficiencies. Our Committee agrees with the findings of the accreditation committee and suggests that EPA devote the necessary resources to bring the RTP animal facility into similar compliance.

2. Staffing for Research

The Committee recognizes the role of history in present EPA staffing, not only the legacies of personnel from the predecessor agencies and programs that were coalesced into EPA in 1970 but also the effects of legislative actions, OMB decisions, and civil service regulations. The Committee, therefore, addressed only limited aspects of the total problem, including the effects of imbalance between funds available for extramural research and professional staff available to monitor the research, the availability of research staff to make effective use of special facilities, and the utilization of scientists from academic institutions to supplement EPA research staff.

Over the past three years, there have been several increases in research appropriations, without proportional increases in personnel (Energy-Environment Act, TOSCA, CAA amendments, etc.). One result is an increase in the burden of monitoring extramural grants and contracts. We found great variability from one research program to another in the distribution and intensity of the monitoring load. There was also much variability in attitudes toward an extramural program. Ideally an extramural project should complement and enrich the intramural scientific endeavor. The individual research worker may or may not wish to expand his (her) own research effort through an extramural grant or two.

The Committee found that some EPA scientists were attempting to monitor six or more extramural projects and had no time for their own research. In one instance, every member of a laboratory division was fully occupied monitoring grants or contracts; there was no intramural research. This is an unsatisfactory method for establishing and maintaining a program of high quality; it is made even worse when appropriations are increased without additional staff increases, as frequently happens.

EPA's special inhalation facilities were costly to build and are expensive to maintain (over $1 million annually for one facility). It is important that such facilities be competently and fully staffed to be effectivly used. In fact, these facilities are seriously underutilized, due both to lack of skilled personnel and to lack of funds for research projects. At the same time multi-billion dollar decisions are being made which would benefit greatly from the kind of information these laboratories could provide (for example, the standard setting for ozone and NO_2).

One practice which increases available manpower and promotes intellectual quality is the exchange of staff between universities, industry, and the Agency (Interagency Personnel Agreement-IPA). The exchange is largely from academic institution to research laboratory, and we found universal enthusiasm for this arrangement within the laboratories. However, there seems to be little systematic effort to recruit IPAs; most of the arrangements develop out of personal acquaintances. While these arrangements are mutually benefical and should be encouraged, EPA has recently adopted a policy which will make university recruitment much more difficult--an academic institution must guarantee a position for a returning IPA. This would severely limit opportunities for young scientists in the early post doctorate period of their careers.

3. Accountability for Expenditures

The Committee did not discover any managerial accounting and auditing efforts within ORD to (a) analyze the success or failure of research projects after their conclusion or (b) apply accounting methods to individual projects to determine dollar allocations to equipment, salaries, travel, and services. There is a remarkable and conspicuous lack of managerial auditing procedures in the ORD operation. After initial formulation of the decision units and their overall budgets, the laboratories are assigned the implementation of projects. In general, it is at the laboratory level that work unit productivity and costs must be tracked on a continuing basis and evaluated for effectiveness and adherence to or departure from categorical costs of ORD operations. The insensitivity to project evaluation after completion of effort was reflected by attitudes of managers and bench scientists. The unawareness of costs was also widespread.

D. The Quality of Health Effects Research

The quality of research in EPA is important not only because any worthwhile research should meet standards acceptable to the scientific community but also for reasons derived from the regulatory nature of the Agency. Presumably all research supported by EPA should be related in the short or long term to the development of a regulation or standard. In this context scientific information is likely to be examined critically in an adversary relationship. Any sloppiness in conduct or interpretation of the work is likely to weaken or destroy EPA's position.

Another characteristic of a regulatory agency is the importance of the credibility of research supported by the Agency. Just as research supported by industry is often suspected of bias, whether justified or not, so research supported by EPA is often alleged to be biased toward the overzealous protection of public health. This question of credibility is a difficult one and is never easily solved. For EPA it implies a great need not only for the highest standards of quality in scientific work but also for active and constant efforts of EPA scientists to participate in and have the support of the scientific community.

It was our experience in visiting the health effects research laboratories and Program Offices that EPA has many scientists who would be welcome in the nation's universities and private research institutions. Many of the scientists we talked to were clearly dedicated to the best traditions of public service in carrying out the missions of EPA. The Committee found areas of high morale and sense of accomplishment, but was disturbed to find areas of low morale and frustration from frequent changes of research direction or even the absence of a sense of direction, often stemming from frequent changes in leadership.

In trying to assess quality, the Committee used what it could of the usual criteria for evaluation. The legal counsel's interpretation of the Privacy Act did not permit the Committee to request a curriculum vitae of any scientist, but many offered them voluntarily. The following information was usually obtained from each research unit: the number of staff with research doctorates; the scientific publication record of the unit, in peer reviewed journals and others; the statistical and computational resources of the unit; the procedures used for peer review; and a sense of the intellectual climate of the unit.

The Committee also examined the procedures used in conduct of "extramural" research through grants and contracts. Consultants were added as necessary to evaluate specific programs and special facilities such as animal housing and care. These and other aspects of quality assurance are described under the headings that follow.

1. Publication and Reporting of Research Results

Scientific investigators are part of a tradition which places great importance on scientific peer review of results prepared for publication in professional journals. As with other characteristics, there was high variability of attitudes and procedures among the different laboratories and divisions of laboratories. Some resembled university laboratories in their emphasis on scientific peer review of research plans and peer review of manuscripts before submission to high quality journals. In these cases publication was seen as an incentive for promotion and professional advancement. Publication in peer reviewed journals enhances the probability that a product of research will "stand up in court." These research units usually had strong interactions with local universities and promoted attendance at scientific meetings, development of symposia and workshops, and participation by IPAs.

At the other extreme were units that appeared to put no emphasis on publication in the scientific literature and who sensed that there was no incentive in EPA for such publication. Others recognized the desirability of such publication but felt so overwhelmed by other responsibilities that they could not find time to publish. Some felt that internal reports were all that the Agency expected.

The policy on review of manuscripts varied from in-house review only to submission of the document to up to five external reviewers. Some scientists not only met the formal requirements but also sent their manuscripts to one or two personal acquaintances whose opinions they particularly valued.

To ensure acceptability of research results, the studies must be reviewed by one's scientific peers and published in a reputable journal. Failure to so treat results of research investigations involves the risk that review will occur at a later date, with possible refutation of results and embarrassment to the Agency. Specific mechanisms must be established to require peer review of ORD results and to encourage prompt publication in peer reviewed journals.

Attendance at professional scientific meetings to present research results is not consistently encouraged.

It has been argued by some laboratory staff that peer review and publication are not necessary for mission-oriented research, the EPA focus. The Committee rejects this viewpoint; applied research, often with short-term goals, must be reviewed and published as surely as that related to more fundamental investigations. Applied research is the final product of years of basic research and should receive even greater review.

2. Quality Assurance in Grants and Contracts

Examinations of this important component of the health effects research program revealed serious problems, which affect in-house performance as well as the quality and relevance of extramural research. One aspect is wide variability in funding from year to year and the assignment of funds without any addition of personnel (this happens with the Energy-Environment "pass-through" appropriation, for example). Another serious problem is the uneven distribution of monitoring responsibility among scientists in a laboratory unit; some are overloaded to the extent they cannot possibly do a satisfactory job.

Both the old and new planning systems give authority to laboratory directors to obtain extramural services through award of contract or grant funds. Laboratory directors rely upon their managers to allocate resources under their jurisdiction to complete work unit tasks. Thus there is local or section management of contractors performing services for ORD. In depth examination of several of the laboratory, sub-unit extramural program procedures for contractor selection, monitoring and evaluation revealed good examples of contractor or grantee selection based on submissions and competitive selection. There were also examples of selection of weak or incompetent applicants, failure of laboratory staff to monitor performance, and almost a total absence of evaluation of the final submission and its relevance to the ORD program and EPA in general.

Some scientists see grants and contracts as a desirable extention of the scope of their personal efforts and enhancement of their contacts with the scientific community. Indeed, a healthy balance between intramural and extramural work can benefit both EPA and the universities. These kinds of relationships do not currently appear to be the norm.

Three kinds of arrangements are used for support of the extramural research program: contracts, grants, and cooperative agreements. Increasingly, contracts have also been used to provide operations and maintenance services directly supporting in-house efforts. The Committee did not systematically examine the quality of contract research and did not look at all of the cooperative agreements, a recent development which has been little used so far.

EPA has more specific requirements for the award of contracts than for grants. The Committee was told repeatedly that grants are being used increasingly, because processing them is easier and takes less time (three or four months, instead of six months to a year for a contract).

Examination of selected files indicated that the review procedures for grants were being abused in at least one laboratory. There were examples of critical reviewers recommending that the work not be funded or stating that the proposed project was only marginally acceptable. Yet the project officer proceeded to rationalize the reviewer's comments and indicated alterations in the study protocol of the grant applicants which would overcome the objections of the reviewers. Because the proposed project review and the project officer's revisions were performed near the end of the Federal fiscal year, the funds were awarded without either further submissions or a modified submission by the applicant. In one example, inquiry revealed that one year later the project monitor still did not know if the grantee had modified the protocol, added additional personnel, etc., as was recommended by reviewers and as was rationalized by the project officer in justification of awarding the grant.

In other examples the Committee found that external reviews were not obtained before award of grants. (Some EPA staff informed the Committee that soliciting external reviews of contract proposals was illegal, except with permission of the applicants.)

Scientists were encountered who had difficulty keeping track of the number of awards they were assigned to monitor; they were not familiar with the details of extramural contract or grant work as it progressed. The quality of investigatory work external to EPA laboratories and supported by ORD funds was highly variable and of great concern, mainly because ORD oversight was usually lacking. It requires project monitoring effort to ensure that contractors or grantees perform responsive work on a timely basis. There is an efficient "mix" of one's own research and that of others that can be effectively monitored. Conversations with ORD laboratory staff suggested that monitoring one or two contracts or grants totalling perhaps $100-150,000 per year would be a stimulus to a senior ORD scientist. More extensive monitoring responsibility is a burden to the ORD scientist and, even more important, he/she cannot efficiently discharge the monitoring responsibilities. Some research units are so heavily committed to monitoring grants and contracts that no scientist in the unit has any time for his/her own research. The lesson is a clear one; Congress should not increase R&D funding without concomitantly increasing ORD staffing or without identifying alternative approaches.

A frequent complaint was that monitoring was handicapped by the absence of travel funds for the project officer to visit the institution where the research was being done.

Grant applications are of two types--solicited and unsolicited. The latter presumably represents the spontaneous interest of university scientists to do research on environmental problems in which EPA might be interested. The common response to the Committee's inquiry was that unsolicited grant proposals have almost no chance of being funded, primarily because they are judged "not relevant." It seems clear that EPA scientists are using grants in lieu of contracts, that they monitor them like contracts, and that there is little opportunity for "investigator initiative."

The mechanisms for soliciting grant proposals vary from one unit to another. We found little evidence that EPA has found effective ways to interest university scientists in its problems on a sustained basis.

Another practice, employed to extend the time for longer-term research but with the potential for abuse, is the "front-end loading" of a newly awarded grant. In this practice the amount of the award may be as much as twice the amount of the first year's budget. The investigator can then request an extension for a second year without additional funds, an action routinely granted without a critical review of research progress. The Committee does recognize the need for assured funding of projects that may require more than one year to complete. However, if funds required for more than the first year's operation must be obligated, the project must be carefully monitored to assure that funds for the second year are required and appropriately used.

Another shortcoming of the present EPA system is the absence of a routine operational audit of the quality of extramural research. Individual scientists and laboratory directors told us that a contractor or grantee who performed poorly was not likely to obtain another grant or contract. This informal and spottily used system is not adequate to assure the high quality of extramural performance.

ORD's entire program to make extramural awards of funds under contracts, grants or cooperative agreements requires a thorough overhauling. Extensive standard operating procedures for awarding grants and contracts exist in the Agency; they are voluminous, difficult to comprehend, and are avoided by laboratory staff. It is necessary to establish simple, explicit procedures to be followed by laboratory directors and scientists throughout the life of an extramural award. At present, laboratory directors are expected to satisfactorily complete work unit tasks; extramural projects are their choice and responsibility. The Committee recognizes the need for extramural assistance, particularly if the trend continues to increase ORD dollars without increasing the number of positions for investigators, but the procedures for extramural programs must be placed on a more defensible basis throughout ORD.

3. Career Opportunities

The civil service system was examined as an influence on the quality of research programs and on career opportunities for EPA scientists. There were several examples of negative effects of the civil service system; for example, it does not permit the flexibility to hire new people or to move people as program orientation shifts. Consequently, there are cases in which excellent scientists are placed on projects where their expertise is not needed and where they have to be "re-tooled".

Although the Committee talked to people who had been promoted because of the quality of their research, more frequently promotion related to the assumption or increase of administrative responsibility. Many times a good scientist makes a poor administrator, but the scientist takes the administrative position for the higher salary, not because he or she has management skills. Talented researchers must be encouraged to continue as investigators. Mechanisms must be instituted to further their professional development and their allegiance to the Agency.

It appears that the policies and procedures for advancement do not encourage the emergence of either top scientific or managerial performance. The system does encourage job-hopping by bright people, particularly those in Program Offices. A promotion ladder based on scientific achievement rather than administrative responsibility would help to solve this problem. Many industrial research laboratories use dual ladders for advancement-- administrative and research. Senior research personnel are rewarded with remuneration and privileges comparable to those of a senior manager. ORD is experiencing difficulty in retaining research physicians, epidemiologists, and toxicologists, among others. At the time of this writing, the Human Inhalation Laboratory in Chapel Hill, N.C., a unique facility, is virtually without physicians to perform the research vital to scheduled regulations in the air media.

Administrative mechanisms should be developed to offer a challenging career ladder to these professionals if first rate health effects research is to be performed in ORD. The Committee recognizes that many of the reforms addressed elsewhere in this report will improve conditions for these professionals, but an explicit analysis of conditions and incentives related to a research career in ORD must be performed and improvements implemented where necessary.

4. Other Components of Quality Assurance

Performance evaluations of individuals and laboratories are often perfunctory. Many individual scientists were unclear about the criteria applied to their evaluations and advancement.

Evaluation of laboratories is not being done in terms of good laboratory practices, rewards and incentives, budget and resource allocations, and accountability.

Personal scientific integrity is difficult or impossible to determine in a study of this kind. To the extent that personal conversations, attitudes expressed, and measures taken to assure the quality of research, design, and analysis can be used to assess scientific integrity, the Committee was favorably impressed. If there were subtle biases in the interpretation of research results, they were not detected in this study.

There are periodic "program reviews" in which headquarters' staff members visit the laboratories. These are described by the laboratory scientists as superficial "show and tell" sessions. There is limited scientific feedback from headquarters' staff, and the only benefit to the laboratory is the stimulus to prepare material for presentation.

By contrast, it was noted that when NIH is involved in a jointly sponsored project, there is a visit by NIH staff members, who conduct an intensive critical analysis of the proposed research project. EPA staff who have thus been "nailed to the wall" to defend their projects say they would welcome this kind of evaluation of EPA projects.

There appears to be a general lack of understanding of the Science Advisory Board and its constituent committees by laboratory staff. In view of this, it was not surprising that the Science Advisory Board was criticized for its lack of scientific interaction, failures in communication, and lack of subsequent feedback.

5. Interagency Agreements

The Interagency Regulatory Liaison Group (IRLG) is a new activity which seems to be off to a promising start. Since it is a developing program, no attempt was made to evaluate it.

Other programs involving interagency agreements have had mixed success, at best. EPA has substantially supported the National Center for Toxicologic Research since its inception, with little evidence of any product benefiting EPA. Disappointment was also expressed about interagency agreements with Los Alamos and Oak Ridge National Laboratories and three of the National Institutes of Health.

A significant portion of EPA's health effects research is supported by interagency agreement for the special Energy-Environment appropriation. No attempt was made to examine this program in detail.

E. Other Relevant Topics

1. Long Range, or Core, Program Research

There are subjects for research which are important to several of the media programs. Examples are the properties of particle dispersions, be they in air or water, because of their relevance to collection of the disperse phase prior to effluent discharge, to particle deposition in the human respiratory tract and to particle retention or solubilization in the human gastrointestinal tract; epidemiological methodology because it is a major tool for relating exposures to pollutants to potential effects in the exposed population; and techniques of risk assessment and presentation of the implications prior to judging acceptability of risk. There should be a long term ORD investment in researchers and facilities to develop highly active and productive groups in those areas of research which are central to large segments of Agency regulatory activity. This investment is currently being augmented by initiation of extramural university centers. It is planned to shuttle ORD staff between their resident laboratories and the centers for "leaves of absence" during which they can pursue studies in core areas while upgrading their capabilities on a university campus. We applaud this plan, but also see the need for small, active core research groups in ORD laboratories. Allocation of a specific percentage, at least 10%, of the ORD budget for relevant research in core subject areas, but not on projects specifically traceable to immediate program needs (6 months-2 years), is a reasonable assignment of funds. There is no obstacle to this programming of funds under the present procedures for funds authorization. They are part of the funds assigned to research for the specific statutes, because results will be applicable to those statutes, as well as to others.

2. ORD/Congressional Staff Information Transfer

The relationship and relevance of ORD projects to regulatory needs is not always obvious, particularly to non-scientists. It is essential that members of Congress and their staffs understand the efforts of ORD. Such understanding does not develop accidentally. ORD should develop a plan to regularly inform interested members of Congress and their staffs of the results of ORD efforts and the manner in which they further the goals of statutes administered by the Agency. ORD's investment in what is essentially an educational program for legislators should involve ORD's most senior scientific staff. It is critical that this communication effort include laboratory personnel who are directly involved in the conduct of research. We note the 1978 and 1979 Research Outlook efforts by ORD, but believe efforts must go far beyond this and must incorporate personal communications, as well as transfer of printed information. The concepts of chronic disease, multiple etiologies of disease, host factors, and cumulative effects, to name only a few, are complex and crucial to understanding the underlying approaches to research in ORD.

VI. UTILIZATION OF ORD RESULTS

Different Program Offices utilize ORD research results to different extents. Senior program managers indicated that they did not look to ORD for results; rather, they sought capable laboratories and investigators related to their needs, be they within or outside the Agency. A Radiation Program manager indicated that ORD has little capability to assist them; ORD has no capabilities in the area of biological effects of noise. ORD appears to have little involvement with the Toxic Substances Office. The Water Program draws heavily on ORD at the present time, and recently ORD had a major involvement in the formulation of criteria documents for 65 water pollutants.

The input of research to the screening test and risk assessment process was clearly evident from the Drinking Water Research Program in Cincinnati and the Pesticide Programs at the Gulf Breeze and Wenatchee Laboratories. Their scientific standing is recognized. The respective leadership has maintained the kinds of communication necessary (with the help of pilot research committees) to keep the personnel in Washington knowledgeable and involved.

It is not surprising to find that the utilization of results from ORD projects is not carefully tracked when the joint planning of research by Program Offices and ORD is in its infancy with the pilot research committee program. Program managers elaborated on many needs not being met by ORD; there were few illustrations of ORD responsiveness to programs and subsequent incorporation of results into regulatory programs. On the other hand, ORD staff were often praised for their responses to requests for preliminary review of regulatory documents, consultation on imminent regulatory submissions to the courts and, in general, what can be characterized as technical support to the Program Offices. The Committee was not able to estimate the average percentage of ORD professional staff time devoted to technical support; it varied with individual research sections. It was clear that in some instances it represented a significant portion of some individuals' time. This technical support has on some occasions played a critical role in the Agency's formulation and defense of regulations.

The ORD function in the Agency is defensible mainly on the basis of program utilization of insights and results developed intramurally or extramurally under its auspices and guidance. The Committee found that ORD did not fully recognize or accept this criterion for judging its efficacy, had not developed mechanisms for efficient utilization of research results by Program Offices, and did not maintain records of results which had been incorporated into regulations.

VII. STATUS OF IMPLEMENTATION OF TWO SETS OF NATIONAL ACADEMY OF SCIENCES (NAS) RECOMMENDATIONS TO EPA

The analytical study of Research and Development in the Environmental Protection Agency conducted by the Environmental Research Assessment Committee (John M. Neuhold, Chairman), of the National Academy of Sciences, National Research Council, in 1974 and 1975 set forth a number of useful recommendations.*

Before that, a Review Committee on the Management of EPA's Research and Development Activities (Robert W. Berliner, Chairman) had developed recommendations submitted to the Agency on August 27, 1974. Our Committee (HERRG), therefore, in its collective judgment, has attempted to evaluate the extent to which former recommendations have or have not been implemented. This final exercise was undertaken at the end of our study when all visits had been completed. It was possible by this means to add a different, but closely related, viewpoint against which to compare our own observations of performance and changes during the past four years.

Although there has been significant improvement in selected aspects of EPA research planning and management, most notably the development of pilot research committees with representatives from across the Agency, the overall planning and management system is still unsatisfactory. Many of the reasons for inadequacies in the system in 1974 still exist today and will be enumerated in the following.

A. _Recommendations from the Environmental Research Assessment Committee of 1975_ **

(1) "EPA's research and development should concentrate primarily on support of the Agency's decision making and anticipation of future problems."

There are improvements arising from better communications between research workers in the laboratories and the Program Offices. The pilot research committees have helped establish communications and understanding.

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*_Analytical Studies for the U.S. Environmental Protection Agency, Volume III_, "Research and Development in the Environmental Protection Agency," Environmental Research Assessment Committee, Commission on Natural Resources, The National Research Council, National Academy of Sciences, Washington, D.C. 1977.

**_Ibid_. page 2.

(2) "EPA should supplement its primary research responsibilities with some fundamental research to help advance understanding in environmental sciences and technology."

Planning for fundamental or longer term research is still inadequate. However, to achieve the right kind of balance there first needs to be a close and direct relationship between researchers and program managers. Both must understand the research process and information needs of the regulatory process.

(3) "A new legislative mandate will be required if EPA is to conduct effective anticipatory and fundamental research."

The HERRG Committee does not agree that additional legislation is needed to fund and conduct "anticipatory and fundamental research."

(4) "We recommend that the Office of Science and Technology Policy (OSTP) develop a federal environmental research, development, and demonstration strategy that includes designation of the appropriate roles of all participating federal agencies and existing interagency coordinating committees, and delineation of the relationships between federal and nonfederal research and development. The OSTP should coordinate the implementation of the strategy through its mandated consultations with the Office of Management and Budget (OMB) about the scientific programs of federal agencies."

This recommendation has not been followed, per se. However, the Interagency Regulatory Liaison Group is seen as an excellent initiative which has the potential of reducing duplication and confusion among agencies. Better coordination of research efforts and better agreement on the methodologies applicable to hazard assessment are encouraged by this Committee.

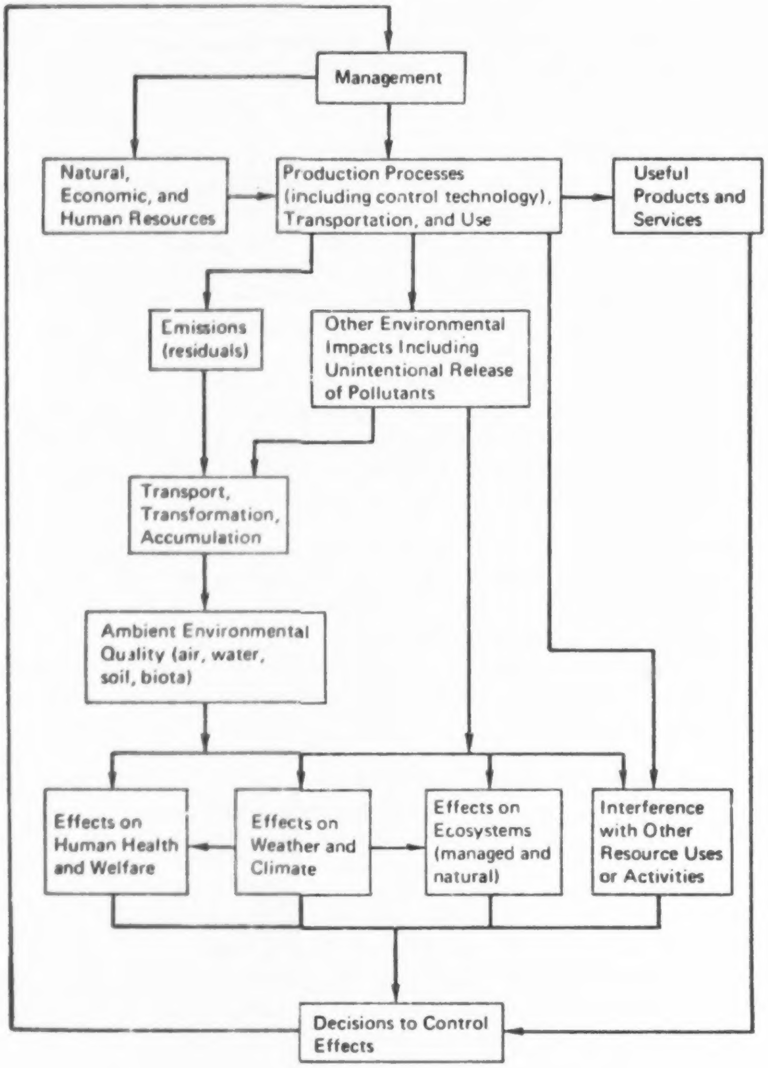
(5) "We recommend that the management of all research and development in EPA be centralized in the Office of Research and Development (OR&D)."

There seems to be progress in centralizing the management of R&D within ORD, but a number of Program Offices administer R&D contracts and grants directly. The Committee urges that this Academy recommendation be implemented to assure that proper oversight and scientific peer review be applied whenever research is conducted by the Agency.

(6) "EPA's research program needs to be better organized for balance and continuity, through planning developed around a logical conceptual framework of environmental protection..."

A number of areas within the present EPA research and development program are still not aligned within a logical conceptual framework of environmental protection and thus are not as effective as they could be. The conceptual framework proposed in the earlier NAS/NRC report (1977) still appears to offer a sound framework for the assessment of research needs, the planning and conduct of research, and the utilization of research results. The framework is shown below:

Framework for Environmental Protection


Management
Natural, Economic, and Human Resources
Production Processes (including control technology), Transportation, and Use
Useful Products and Services
Emissions (residuals)
Other Environmental Impacts Including Unintentional Release of Pollutants
Transport, Transformation, Accumulation
Ambient Environmental Quality (air, water, soil, biota)
Effects on Human Health and Welfare
Effects on Weather and Climate
Effects on Ecosystems (managed and natural)
Interference with Other Resource Uses or Activities
Decisions to Control Effects

> (7) "A central function of scientific support to decision making should be to provide integrated assessments of available scientific, technical, and economic data pertinent to pending decisions in forms suitable for use by Agency decision makers. We recommend that the importance of this function be recognized by giving it formal status and organization in OR&D."

The importance of integrated assessments continues to be recognized, and the Agency is moving toward establishing the formal organization required to make such assessments. When such an organization is fully operational, it should be of major assistance in providing information that is useful to the regulatory decision makers; but of equal importance is information that is crucial for the planning of a responsive research program. Carefully conducted assessments can identify gaps in research information or parameters that have the greatest influence on the effects of emissions. In the absence of such assessments there is a risk that research efforts may be directed to developing information that may have limited value in establishing or reassessing standards or in guiding their enforcement.

> (8) "The research planning system now in use in OR&D, characterized as "top-down" in structure, should be retained for research in support of decision making. For anticipatory and fundamental research, however, we recommend a "bottom-up" scheme that relies on the scientific community to identify research needs."

Except for the pilot research committees, the planning process remains "top-down." Substantial improvements are needed to achieve involvement of those generating and using the data.

> (9) "We recommend that block funding of extramural grants, contracts, and interagency agreements be considered as a mechanism to establish centers of excellence, federally funded contract research and development laboratories, and umbrella interagency agreements to supplement the intramural research and development program."

To date, block funding mechanisms have not been extensively used by ORD, although legislation has provided the opportunity for use of cooperative agreements that may very well match ORD needs. ORD has made preliminary plans for using such agreements and should proceed expeditiously to implement their use. Such agreements offer an opportunity for a complementary approach to the present system of grants and contracts for extramural performance.

(10) "All proposals and completed research should be subjected to review on their technical merits by scientific and technical peers."

Peer review of proposals and completed research was inconsistent and, in many cases, inadequate.

(11) "We recommend the use of a parallel grade advancement system, based on performance of research, that does not require researchers to assume administrative or managerial tasks to attain promotions."

There was little evidence of implementation of a parallel grade system. In some cases, individuals have accepted administrative or managerial assignments based on the perception that such assignments are critical to obtaining promotions.

B. Recommendations of the Review Committee on Management of EPA's Research and Development Activities *

The Review Committee report noted that the present (1974) "Office of Research and Development planning and management system fails to meet the needs of the Agency" and proceeded to identify two main categories of failure: (1) the nature of the system itself and (2) external constraints as perceived by the Office of Research and Development and communicated to the Review Committee.

1. The nature of the system itself.

a. "Planning is separated from responsibility for execution, leading to severe resentment among performing researchers. The assignment of responsibility for specific actions and decisions is difficult."

There is still an inadequate linkage between planning and responsibility for execution that is apparent, in varying degrees, at all levels of the organization below the Assistant Administrator for Research and Development. An individual researcher charged with responsibility for performing a task may have no input to the planning of that task.

b. "Priorities do not reflect the needs of regulatory offices and regional offices because of the 'vacuum cleaner' approach to soliciting ideas, and the system-induced barriers to using common sense in the selection process."

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*_Ibid_. page 96.

There has been improvement in the establishment of priorities in selected areas, most notably those for which pilot research committees have been established, to yield a research program potentially more responsive to the needs of the Program Offices. In other areas, the research program is less clearly defined and priorities have not been established. Faced with necessarily limited resources, the responsible individuals have frequently elected to continue work in all areas at a reduced level of effort rather than electing to eliminate or defer the lowest priority projects. The result is a reduced potential for success in the highest priority areas because of lack of funds.

c. "Inadequate attention has been paid to the possibility for trade-offs, or modifications in budgeted costs, among various projects. This has aided in the development of a situation where there is only a series of discrete projects and no Agency program. This situation is further aggravated by the absence of long-term (3-5 year) planning."

Long-range planning within the Agency remains inadequate. The large portion of the planning within ORD is necessarily dependent upon the needs identified by the Program Offices. These long-term needs have often been inadequately stated, if at all, thereby handicapping the development of a responsive long-term research plan. It was originally anticipated that the pilot research committees would develop a strategic plan for their areas of responsibility. However, this was not done, in part because of the timing and pressure of the ZBB process which forced the pilot research committees to take a shorter-term outlook. An additional factor which should also be recognized is the reluctance of some individuals to engage in defining a strategic plan until they are certain that managers are serious about the effort.

d. " The complexity of the system makes it counter-productive. The large amount of paperwork and excessive bureaucratic review is a wasteful consumption of time and energy. The needs of the Agency are complex; however, this does not change--but rather heightens--the need for a simple and understandable planning and reporting system clearly directed by the Assistant Administrator and in which field personnel have a real participatory input."

The planning and management system is still extremely complex, involves a large amount of paperwork, and is often a waste of valuable time and energy. An inadequate amount of authority has been delegated downward to the laboratory directors and lower echelons of the Agency. In those cases where authority has been delegated, there appear to be excessive requirements for keeping all upper levels of the Agency informed. One example is the use of the highly structured quarterly "Project Status Reports," which include detail at the task level (tasks ranging in expenditures of less than $10,000 to over $200,000 per year); the volume of material developed at the laboratory scientist's level is passed successively to the Division Director, the Accomplishment Plan Manager, and the Office of Health and Ecological Effects and its various staff units.

e. "Accountability is made impossible by the parallel but separate management systems--some for housekeeping and the others for program content--and by the hopelessly complex Program Area Manager-Program Element Director-Program Assessment Group-Strategies system which obfuscates management responsibility."

The chain of accountability is extremely difficult to trace from the laboratory scientist (either in-house or engaged as a contractor or grantee) to the Assistant Administrator for Research and Development. The "chain of command" is excessive with numerous intermediate steps that serve only to delay or, in some cases, reprocess information without serving any clear management functions to enhance research productivity, efficiency, or responsiveness. Indeed, in many areas the number of information reprocessors and/or relayers makes it difficult to identify the laboratory scientist.

f. "Excessive requirements for detail at all planning levels lead to an oversized headquarters staff and to the stifling of innovation in the laboratory."

The level of detail required at all levels and the transfer of materials with limited informational or management value continues to contribute to the maintenance of an overly large Washington staff. In what appears to be a contradiction, the Washington staff is understaffed in relation to the amount of material being transferred and processed. Unfortunately, much of this effort is misdirected. Because of the attempts to maintain detailed accountability of even extremely small projects, the innovative responsibilities of the laboratory scientists continue to be unfulfilled.

g. "The existing management structure does not allow for the corrective feedback and flexibility which are essential to any successful research and development program."

Because the "chain of command" is so long and the communication pathways are jammed with trivia, corrective feedback does not occur at the level required for effective management. The rigid system of accountability to the laboratory directors diminishes the flexibility needed for operation of a responsive and innovative research program.

h. "A long-term program designed to meet stated goals is missing and this is vital for any scientific venture."

The ORD program has few clearly stated long-term strategies, specific to each Program Office, with easily identifiable objectives and goals. In the absence of long-term objectives and goals, the Agency's research and development resources seem excessively preoccupied with meeting short-term goals, some of which are restatements of goals not previously attained.

i. "A false sense of control is generated by the highly structured mechanism for planning."

The highly structured planning and control system, which generates considerable activity, has promoted the feeling that something is happening that is of a positive nature. The widespread lack of clearly stated and agreed upon long-term objectives and goals, however, makes it difficult to determine whether the movement is positive, negative, or random in nature.

j. "Relationships between the headquarters and field are strained at best; a state of frustration in the field staff is apparent."

Considerable frustration is apparent in many of the organizational units below the Assistant Administrator's office. In many cases, the individuals have resigned themselves to tolerating a work environment that is constantly changing, but rarely for the better.

2. External constraints as perceived by the Office of Research and Development.

a. "Enabling legislation is noncoherent and mandates a set of unbalanced and uncoordinated research objectives and timetables."

The enabling legislation for the Agency has been and continues to be viewed as noncoherent, mandating a set of unbalanced and uncoordinated research objectives and timetables. Since the enabling legislation has not and may not be changed in the near future, ORD has no real choice but to accept the situation that exists and strive to adjust its planning and operations accordingly.

> b. "The lack of an integrated approach to environmental pollution control in the Agency as a whole makes an integrated research and development program very difficult to form."

Although some individuals view the Agency as not having an integrated approach to environmental pollution control, some progress has been made, and the use of approaches such as the pilot research committees offers the opportunity for developing an integrated research program with long-range objectives and goals as recommended in 1974.

> c. "Civil Service rules, parochial political pressures, and human nature combine as barriers to the simplification, assembly into 'critical masses,' and logical organization of the research units which were inherited by EPA when it was created."

Civil service rules, parochial political pressures, and human nature continue to be barriers to simplification, assembly into "critical masses," and logical organization of the research units. Of perhaps equal importance has been the failure to recognize that in the absence of a clearly recognizable research and development strategies specific for the Program Offices, the constraints of civil service rules, the influence of political pressures, and human nature will have substantial adverse impacts on the research program. An identifiable strategy with well thought out objectives and goals will go a long way toward minimizing the impact of factors that can push a reaction-oriented program, with ill-defined objectives and goals, off course. As addressed elsewhere in this report, civil service rules do adversely impact the research program, and suggestions for change are offered. However, in the absence of changes in the rules, the situation must be accepted and plans developed within the constraints of the rules. Parochial political pressures have been, and probably will continue to be, brought to bear. However, it should be recognized that the Agency has strong political supporters, who can counter parochialism if they know that the Agency has a research program that is scientifically and managerially sound and programatically responsible with a plan for the future. Without question human nature may at times offer constraints, but, if properly directed, can also provide forward momentum.

> d. "A level budget (except for the energy 'roller coaster' of FY 74,75,76) prevents transitions which would be possible in a steady growth situation. An internal 'roller coaster' budget appears to be particularly disruptive to individual projects."

The level budgets of fiscal years 1974, 1975, and 1976 were given as the reason for the failure of the ORD planning and management progression. The level budget was said to prevent transitions that would be possible in a steady growth situation. Recent budgets have shown an increase; however, transitions do not appear to have occurred any more smoothly. A concern raised even more frequently than the shortage of funds is the restriction on the number of full-time employees. Although the impacts of the restriction are real, little has been or is likely to be accomplished by merely accepting the OMB mandated personnel ceilings until they can be changed. Until changes are made, it would seem prudent to exercise greater care in the use of available personnel and to have a strategic plan for addition of personnel when vacancies do occur. Such a strategy for the management of personnel resources is an essential part of the total Agency research and development plan and is the only way the personnel resources (as to number of individuals with specific types and levels of disciplinary training) can be matched to the long-term needs of the Agency.

The 1974 letter report of the NAS/NRC Review Committee listed four major recommendations.* The recommendations have been implemented to varying degrees and, even where not fully implemented, still seem appropriate. Because they are still germane, each is reviewed below.

> 1. "The Environmental Research Objective Statement-Research Objective Achievement Plan-Program Area Manager-Program Element Direction-Program Assessment Group-system should be abolished. Responsibility for carrying out a program designed to meet the goals of the Office of Research and Development should be delegated directly to the National Environmental Research Center directors. Resources of manpower and money should be allocated directly to each National Environmental Research Center."

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*Ibid. page 98.

-- The planning and management system referred to has been largely abolished. It has not been replaced by a system that is understandable to all parties involved; thus vestiges of the old system remain. The five Pilot Research Committees cover a portion of the ORD program and partially meet the planning function requirement. The National Environmental Research Centers and related field stations in existence in 1974 have since been separated into 15 individual laboratories, which report through four deputy assistant administrators to the Assistant Administrator for Research and Development. Although allocations of resources are made directly to the individual laboratories, there appear to be numerous strings attached which severely restrict the authority of the laboratory directors.

2. "The line reporting within the Office of Research and Development should be from the National Environmental Research Center directors to the Assistant Administrator. The Assistant Administrator should have a small staff to perform only staff functions and not to serve as a filter or layer through which the National Environmental Research Center directors report. This should develop into a simple pyramidal management system through which all direction, supervision, and evaluation is accomplished. This would, in effect, eliminate all layers or parallel management plans and result in a clear chain of authority from the individual researchers to the Assistant Administrator for Research and Development. The pyramid should decentralize quickly from Washington Headquarters to major field units. The Headquarter's staff should be trimmed appropriately and those necessary for "Washington liaison" activities clearly labeled. We did not have sufficient time to evaluate the role and position of the Washington Environmental Research Center. Such an evaluation should be made.

   "Because of the recent formation of the Agency by coalescence of disparate portions of other agencies, a particular need for intra-agency communication exists. To this end, a planned continuing rotation of field personnel into and back from a small Headquarters staff unit and between other units should be carried out. Short term, non-government talent should also be worked into this rotation system."

--The Washington staff of ORD is still quite large with a relatively large number of individuals serving in special staff roles and on numerous ad hoc committees. Clear chains of authority do not exist between individual researchers and the Assistant Administrator for Research and Development; rather there are numerous filters through which information exchange must take place. Despite the largeness of the Washington staff, many appear overwhelmed by their work load, while others apparently fill slots for which there are no longer meaningful work assignments. Approximately 90% of the work load seems to be carried by one-half of the staff.

Communication between Program Offices and the Office of Research and Development has been virtually non-existent in some areas. The five recently organized pilot research committees appear to have helped improve intra-agency communication and offer considerable promise for further improvement.

Rotation of field personnel into and back from headquarters has occurred to a limited extent, but more exchanges are needed. A limited number of short-term, nongovernment individuals have rotated through the system, however more exchanges of this type are also needed.

3. "The function of the Assistant Administrator for Research and Development should be to assemble, analyze, and clearly define Agency research and development needs and objectives with the participation of the other Assistant Administrators and the National Environmental Research Center directors as the mechanism to develop goals, programs, and priorities. He should allocate objectives and the resources for their accomplishment to the National Environmental Research Centers. Once allocation is decided upon, the performer of the research or development should be linked directly to the user of the projected output for information exchange.

"A performance evaluation should be set up to include continued inputs from users, and outside visiting committees reporting at a high level should be regularly employed. The system of visiting committees employed by the National Bureau of Standards should be studied for applicability.

"A plan for a 3-5 year period to be revised at least annually should be developed."

--The Assistant Administrator for Research and Development has not systematically assembled, analyzed or clearly defined research and development needs and objectives. "The Research Outlook: 1978-1983", which has been published, and "The Research Outlook: 1979-1984", currently nearing completion, are perhaps the most definitive statements of research and development needs and objectives. However, neither document is an adequate statement of near-term, mid-term or long-term plans and objectives. Participatory discussions have apparently occurred with laboratories. Until initiation of the pilot research committees, most planning activities were carried out in headquarters with only limited and late stage input from the laboratories. With the advent of the pilot research committees, laboratory and Program Office input to near-term research planning has occurred in those research areas for which committees have been developed. This has had a positive impact on planning; however, in most cases where the laboratory director was not involved in the committee's activities, it has minimized the role of the laboratory director in the planning process. For a majority of the research programs, the laboratory directors and staff have been involved primarily in near-term planning and then most frequently at late stages of the budget cycle. In many cases the input has been fragmentary and spurious, i.e., "What would you and your people like to do next year?"

Resource allocations (personnel and finances) are in a continuous state of flux. As expected in relation to the Federal budget system, changes are made up to the beginning of the current fiscal year, but frequently continue on throughout the year. The major certainty appears to be that change will take place. The laboratory directors apparently are given little authority for shifting resources within program areas and even less authority for shifting resources between program areas. This lack of flexibility, with continuous management from headquarters, appears to have had a negative impact on the productivity of the programs. EPA scientists, in many cases, are confronted with changes in program direction and level of effort with very short notice. Extramural projects have, in many cases, been treated as the most flexible portion of the system. Contracts that have been expanded or shifted in direction on very short notice have served to alienate substantial portions of the research community. Precipitous actions, discontinuation of programs, or shifting of program direction raises legitimate questions concerning the adequacy of Agency research and development planning. Precipitous increases of funds, although having associated moments of elation, are usually followed by a recognition that the time and personnel resources available do not allow careful selection of new contractors, resulting in projects that are less successful than they should be.

4. "Not only the changing nature of environmental problems but also the exigencies of the economy, suggest that it would be inadvisable to build up a large permanent staff. Rather, maintaining the necessary competence to monitor grant and contract work as needed would appear to be a prudent course.

"A careful review of the contract and grant procedures should be undertaken."

--The Agency has not given adequate attention to developing a strategy for the implementation of its research program, i.e., balance among intramural research, contracts, grants and interagency agreements. Although the mandated ceiling on numbers of personnel is recognized, the Agency has not made adequate plans for living within that ceiling. To circumvent the personnel ceiling, contracted personnel are used on site at many laboratories to perform maintenance operations, thereby extending the work force. There are numerous individuals who are faced with a multitude of competing responsibilities: performing hands-on research; supervising technicians who directly assist them; preparing orders and monitoring the efforts of on-site contract personnel; soliciting and reviewing research grants and proposals; monitoring research being performed by contractors and grantees, either by personal visit or review of innumerable reports expected of the contractors and grantees; and participating in the preparation and review of criteria documents and related material. In some instances, there are experienced scientists and managers available who do an excellent job of balancing and meeting these competing demands. In a few instances, individuals, who have been unwilling to accept the demands placed on them, have retreated into their corners to do "their thing," i.e., perform specific research in line with their interests, and are content to let the system go on its own merry way. Although this has solved their immediate problem, it has increased the workload and demand placed on their colleagues. In many cases, the demands are excessive in relation to the experience and training of the staff member, and one or more of the aspects of the job are performed poorly.

The impact on both intramural and extramural research is apparent. The impact on the intramural program is discernible by the fact that many EPA scientists do not publish because they have performed relatively little research. A review of how selected grants and contracts were initiated and monitored suggests that, in some cases, the individuals involved did not have adequate experience or time to perform their assignments. A related and contributing factor has been the development of an "unwritten" set of procedures for promoting the use of grants rather than contracts because of the more cumbersome nature of the contract award process.

In summary, a careful review of contract and grant procedures is as much needed now as it was at the time of the NAS/NRC report. A key aspect of such a review should be the development of a strategy dealing with how much research can be appropriately performed in the Agency and how extramural work can best be performed.

VIII. COMMUNITY HEALTH AND ENVIRONMENTAL SURVEILLANCE SYSTEM (CHESS): AN INVESTIGATIVE REPORT

A. Background of the CHESS Program

The Community Health and Environmental Surveillance System (CHESS) was initiated about 1970 and involved collection of data during the period 1970 to 1975. This research and surveillance program was designed to investigate the relationship, if any, between air pollution and health in human populations (up to a few thousand persons), studied at single contacts or followed for short periods of time (up to two years), for characterization of health status. These observations were coordinated with observations on air pollution in the environments of the study populations. The populations and areas included for study were selected to represent pairs or larger sets of contrasting exposures, for example, a "clean" and a "dirty" town or a series of several communities with a known or suspected substantial range of air pollution conditions. Most populations consisted of persons not previously known to have any special health problems, although some studies within CHESS were directed at groups defined by disease conditions, for example, known asthma patients.

The program operated from 1970 to 1975 and resulted in a major publication in May 1974 (Health Consequences of Sulfur Oxide: A Report from CHESS, 1970-1971). That publication included analysis and interpretation of the first two data collection years. Other smaller papers and presentations involved these and some later years' data. The major review in 1974 implicated sulfates, sulfuric acid, and sulfur dioxide as causing health effects, chiefly respiratory tract disease or disturbance of pulmonary function, at or near levels of these pollutants commonly considered "safe." That report was extensively reviewed by a number of individuals and groups and received both praise and criticism. In part because of some of the criticism, CHESS, in its original form, was discontinued. It was recommended, however that additional substantial efforts be made to optimally use the collected data beyond those uses reported in 1974. Special features to be considered in further work were to include: (1) analysis of extensive data collected from 1973 to 1975 and not included in the 1974 report; (2) improvements of statistical data and analytic techniques; (3) assessment of validity of coded data and of extent of coding errors or other correctable problems in the data set; (4) increased objectivity in interpretation of findings; and (5) assessment of confidence range of estimates of pollution.

B. Findings of the Subgroup

During the site visit in September 1978, the status of the CHESS program was reviewed and a summary follows. The mechanism for continuing work on CHESS is a contract from the Environmental Protection Agency to the University of North Carolina, Chapel Hill, principal investigator Dr. Carl Shy. This contract work is closely followed by members of the epidemiology division and the statistics unit of the Health Effects Research Laboratory, Environmental Protection Agency. Dr. Shy was formerly extensively involved with the CHESS project as a member of the epidemiology unit; he is now a member of the faculty, University of North Carolina. The plan is to review all of the CHESS data collected for 1970 to 1975. The contract to the University was let in September 1977.

To date there has been a major effort to validate the CHESS data sets. This was projected to require two years but is now expected to be completed about eight months ahead of schedule because special priority was given to the validation project. This has been accomplished in spite of a budget deletion of the funds planned for this purpose, thereby making it necessary to discontinue other work to meet this mandated task. The validation project is designed to identify discordances between manually recorded original data and tape recordings on exposure (pollution), outcome (health measures), and control demographic and confounding variables. It is being done very effectively under the direction of Mr. Gerald Nehls, Director of the Data Management Unit in the Health Effects Research Laboratory. It must be noted that any validation of these old data is now limited to validation of the previous coding and automating and not to any review of the correctness of initial observations of symptoms and other health effects.

A standing committee has been created, reporting to Dr. Shy and supported under the research contract, to review all planned publications of the CHESS data. The committee presently consists of Dr. Warren Winkelstein (University of California), Dr. James Grizzle (University of North Carolina), and Dr. Michael Lebowitz (University of Arizona). This committee has just been funded, and its effectiveness cannot yet be judged. The membership seems appropriate, and the plan for a standing procedure for outside review is a useful move in response to criticism regarding objectivity of reporting.

A report of a current analysis of a portion of the CHESS data from the Southeast region (Charlotte, North Carolina and Birmingham, Alabama) was presented to the site group by Ms. Shi-Ping Lan. The analysis and presentation indicated a high degree of statistical competence and good collaboration among Dr. Shy, Ms. Lan, and Dr. Hasselblad of the Health Effects Research Laboratory. The material presented will presumably be in a form for publication soon. A principal feature of the new analysis is more adequate use of the symptoms data from the health survey, employing a 5-level symptom scale rather than the dichotomy used in earlier analyses.

The information that can optimally be obtained from this Southeastern study is limited, however, because any possible effect of air pollution on the measured health indices is lower by factors of 10 to 100 than effects of smoking or job exposure. Even though a pollution (intercity) association is found, it remains possible that this association is not causal but is due to a variable related to the stronger effects of smoking or job exposure or to other confounding variables for which no observations are available.

While the acronym CHESS is understood to apply to the 1970 to 1975 group of studies, certain new work in progress follows the general outline of that program. The study most clearly conforming to that design is in four Utah communities, in which 1976 observations are being compared with former 1970 CHESS observations of chronic respiratory disease and of acute lower respiratory tract disease, as related to increasing SO_2 pollution in the region.

A substantial change in the operation of CHESS and related studies has been made in the past three years with a change in emphasis from in-house research to research grants and contracts. This appears to be a result, in part, of the extensive criticism of the previous CHESS program and is reflected in the entire activity of the Epidemiology Division. Only four professional researchers from a previous epidemiology staff of 15 remain in that division. Three new, young junior investigators have recently joined the division. The reduced staff is essentially completely occupied with their duties as project officers on contracts and grants. The result of this change from intramural to extramural with regard to CHESS appears not to be obstructive and may offer certain advantages.

C. Steps Taken by EPA to Meet Brown Committee Recommendations

Public Law 95-155, passed by the 95th Congress, mandated a review of and a report on "the findings and recommendations of the report to the House Committee on Science and Technology entitled 'The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report.'" It was further specified that special attention be focused on "procedural safeguards required to preserve scientific integrity of such research and to insure the reporting and use of such research in subsequent recommendations."

Although Chairman Brown emphasized the desirability of a positive attitude in the letter of transmittal of the Committee Report, the document impressed some members of the subgroup as often being hypercritical and demanding an approximation to perfection that is not obtainable in studies of human populations. The EPA has published a response to the recommendations of the Investigative Committee in the EPA Research Outlook of March 1978. The report of this subgroup will address only those recommendations that deal with on-going activities related to CHESS or other epidemiological and biostatistical work at HERL/RTP. Recommendations will be identified by the numbers used in the Investigative Report and in the Agency's response.

3(a): EPA should publish an announcement regarding the limitations of the CHESS Monograph.
3(c): EPA should publish an addendum to the CHESS Monograph including most of the Investigative Report.

Subgroup findings: It is believed that the EPA response covers these recommendations satisfactorily, although it is difficult to see how the response can be delivered to all holders of the CHESS Monograph. Most scientists, however, will be aware of the limitations of the data in this Monograph.

4(a): Legislation should be reexamined regarding unrealistic procedures and schedules.

Subgroup findings: The legislative mandate for a study of air pollution and its effects on the Gulf Coast (Houston) area appears to require an unreasonably rapid approach to a very complex problem. The epidemiology group expressed an interest in investigating this situation in a systematic, planned fashion. They doubted that the mandated crash approach would be maximally productive but stated their intent to obtain as much valid data as possible. It is not known to what extent this legislative mandate was reexamined. No evidence was found at this level to indicate that reexamination was effective in producing any important changes. Current procedures referred to in the Agency's response in the EPA Research Outlook do not appear to be adequate to solve problems caused by unrealistic legislative mandates.

4(d): EPA should advise Congress if budgetary restrictions will impact completion of major projects.

Subgroup findings: Budget restrictions forced the statistical unit at HERL to discontinue other work to "clean" the data tapes for continued CHESS analyses. The response of the Administration and of Congress to this restriction is not known. While it did not affect CHESS, it must have had an adverse effect on other programs.

5: OMB should be asked to develop procedures for prompt review of questionnaires.

Subgroup findings: The Population Studies Division has found OMB responsive to their need for quick approval of questionnaires. The subgroup supports the EPA position that its questionnaires for volunteers in research projects should not require submission to OMB.

6(a): CHESS data analyses should be carried out only on data with high validity potential.

Subgroup findings: Dr. Shy's group at the University of North Carolina and the epidemiologists and statisticians at HERL have reviewed the CHESS data and have decided which data sets warrant analysis for publication.

6(b): EPA should publish research in refereed journals in a timely fashion.

6(c): EPA should not publish large projects solely in monograph form.

6(d): EPA should not initiate projects for policy consideration unless they can be completed in a realistic time frame.

Subgroup findings: Staff indicated their desire to see results published in scientific peer reviewed journals but emphasized their lack of time to do or report their research or the findings of contractors. It is reasonable to assume, however, that most grant recipients and contractors will publish their findings in appropriate journals. It should be noted, however, that a document entitled "CHESS Bibliography, December 1, 1977" lists, for the period 1/75 to 12/77, only one journal article, seven government publications, and ten EPA in-house publications, plus three more in-house publications that are undated but whose authors or titles suggest that they belong in this time period. For 1977, the bibliography lists only one government publication, which must have been planned well in advance of the Brown Committee report.

It seems unlikely that the EPA responses to this recommendation can be properly assessed until the epidemiologic staff is increased to a size more commensurate with its duties.

7(a): EPA should strengthen the CHAMP aerometric and quality control programs.

7(b): EPA should shorten the time between data acquisition and quality assurance analysis of data.

7(c): EPA should stop employing development stage instruments before qualification testing.

7(d): EPA should not use laboratory models of instruments in the field until they have been field checked and operating personnel trained.

7(e): EPA should reevaluate the opening of the CHAMP operations contract to competition.

Subgroup findings: CHAMP is no longer at HERL. We were informed that it no longer exists as an identifiable unit separate from other monitoring activities.

7(f): EPA research and monitoring personnel should closely coordinate regarding chemical species.

Subgroup findings: Coordination of CHAMP with health effects personnel is now potentially more difficult because of the transfer of the responsibilities of CHAMP to another laboratory. It is still too early to tell whether the transfer will help by strengthening this type of monitoring activity or will hinder the accomplishment of the Agency's mission by impeding coordination.

10(a): An interdisciplinary task force should draw up an integrated air epidemiology exposure assessment program plan for EPA.

Subgroup findings: There is a desire for an advisory group not only to meet this recommendation for assessing health effects of air pollution but also to provide consultation for other epidemiologic studies, both intra- and extramural.

10(c): EPA should have epidemiological questionnaires and panel selection criteria approved by peer groups.

Subgroup findings: Aside from a comparison of self-administered versus interviewer-administered questionnaires, the work related to this recommendation is limited to the information that can be gathered from the extensive analyses of CHESS data being carried out by Dr. Shy. The panel data are not scheduled for analysis.

Planning for a second round of CHESS or for investigation of air pollution "episodes" was not mentioned. It is difficult to see how very much can be done along this line with the limited staff. It seems reasonable to delay planning for a second round of CHESS until the current analyses are completed.

APPENDIX A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 12 1978

THE ADMINISTRATOR

TO: Dr. Emil M. Mrak
Chairman
Executive Committee, Science Advisory Board

THRU: Dr. Richard M. Dowd RMD

SUBJECT: Charge to the Science Advisory Board's Health Effects Research Review Group

The Authorization Act of 1978 for Research and Development, PL 95-155, requires that a special evaluation report on the Agency's health effects research efforts be prepared by the Science Advisory Board (SAB). The Act specifically outlines what is expected to be included in the report regarding your assessment of our health effects research programs, and the procedures for the conduct, review, reporting and use of such research.

To delineate the Congress's charge more sharply, I urge the Study Group to define health effects research to include all planned activities, collection and analyses of data done within the Agency for the purpose of adding to the scientific basis for understanding the effects of environmental factors on human health. This definition would include those activities within the Agency which may be used to assess human risk, and which support standard setting and regulatory decisions, and any activity which gathers new knowledge about human health, or improves our understanding of human health either directly or which can be used to extrapolate to human health impacts. I am happy to hear that Dr. James Whittenberger and Dr. Roger McClellan will chair and co-chair this review group.

I can assure you that your assessment of the Agency's activities within the scope of this definition will be appreciated and that you will have our full cooperation in this endeavor.

Douglas M. Costle

Public Law 95-155
95th Congress

An Act

To authorize appropriations for activities of the Environmental Protection Agency, and for other purposes.

Nov. 8, 1977
[H.R. 5101]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Environmental Research, Development, and Demonstration Authorization Act of 1978".

Environmental Research, Development, and Demonstration Authorization Act of 1978.

SEC. 2. (a) There are authorized to be appropriated to the Environmental Protection Agency for environmental research, development, and demonstration activities for fiscal year 1978--

(1) $92,500,000 for water quality activities authorized under the Federal Water Pollution Control Act of which—

33 USC 1251 note.

(A) $25,200,000 is for the Health and Ecological Effects program;

(B) $9,300,000 is for the Industrial Processes program;

(C) $6,069,000 is for the Monitoring and Technical Support program;

(D) $22,300,000 is for the Public Sector Activities program; and

(E) $29,631,000 is for the Energy program.

(2) $10,800,000 for activities authorized under the Federal Insecticide, Fungicide, and Rodenticide Act, in the Health and Ecological Effects program.

7 USC 136 note.

(3) $16,000,000 for water supply activities authorized under the Safe Drinking Water Act, in the Public Sector program.

42 USC 300f note.

(4) $8,200,000 for toxic substance control activities authorized under the Toxic Substances Control Act, in the Health and Ecological Effects program.

15 USC 2601 note.

(5) $830,000 for radiation activities authorized under the Public Health Act, in the Health and Ecological Effects program.

42 USC 201 note.

(6) $35,000,000 for air quality activities authorized under the Clean Air Act, which shall be in addition to funds previously authorized in the Clean Air Act Amendments of 1977 (Public Law 95-95), so that the total amount authorized for such activities in fiscal year 1978 is $155,000,000, of which--

42 USC 1857 note.
***Ante*, p. 685.**

(A) $36,000,000 is for the Health and Ecological Effects program;

(B) $11,000,000 is for the Monitoring and Technical Support program;

(C) $7,000,000 is for the Industrial Processes program; and

(D) $101,000,000 is for the Energy program.

(7) $31,273,000 for interdisciplinary activities, of which—

(A) $9,230,000 is for the Health and Ecological Effects program;

(B) $6,066,000 is for the Industrial Processes program;

(C) $1,599,000 is for the Public Sector Activities program; and

(D) $14,378,000 is for the Monitoring and Technical Support program.

(b) In addition to any other sums authorized by this section or by other provisions of law—

(1) there are authorized to be appropriated to the Administrator of the Environmental Protection Agency for fiscal year 1978, $10,000,000 for long-term research and development in accordance with section 6 of this Act;

(2) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $2,000,000 for training of health scientists needed for environmental research and development in fields where there are national shortages of trained personnel; and

(3) there are authorized to be appropriated to the Administrator, for fiscal year 1978, $3,000,000 to implement the study authorized in section 103(d) of the Clean Air Act Amendments of 1977 (Public Law 95-95).

Ante, p. 687.

Appropriation authorization.

(c) There is authorized to be appropriated to the Administrator $19,000,000 for fiscal year 1978 for program management and support related to environmental research and development.

Transfer of funds, restriction.

(d) No funds may be transferred from any particular category listed in subsection (a) or (b) to any other category or categories listed in either such subsection if the total of the funds so transferred from that particular category would exceed 10 per centum thereof, and no funds may be transferred to any particular category listed in subsection (a) or (b) from any other category or categories listed in either such subsection if the total of the funds so transferred to that particular category would exceed 10 per centum thereof, unless—

(1) a period of thirty legislative days has passed after the Administrator of the Environmental Protection Agency or his designee has transmitted to the Speaker of the House of Representatives and to the President of the Senate a written report containing a full and complete statement concerning the nature of the transfer and the reason therefor, or

(2) each committee of the House of Representatives and the Senate having jurisdiction over the subject matter involved, before the expiration of such period, has transmitted to the Administrator written notice to the effect that such committee has no objection to the proposed action.

Sec. 3. Appropriations made pursuant to the authority provided in section 2 of this Act shall remain available for obligation for expenditure, or for obligation and expenditure, for such period or periods as may be specified in the Acts making such appropriations.

Budget projections.
42 USC 4361a.
42 USC 4361.

Sec. 4. The Administrator of the Environmental Protection Agency, in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94-475, shall include budget projections for a "no-growth" budget, for a "moderate-growth" budget, and for a "high-growth" budget. In addition, each such annual revision shall include a detailed explanation of the relationship of each budget projection to the existing laws which authorize the Administration's environmental research, development, and demonstration programs.

Public sector agencies, grants.
42 USC 300j-3a.

Sec. 5. (a) The Administrator of the Environmental Protection Agency shall offer grants to public sector agencies for the purposes of—

(1) assisting in the development and demonstration (including construction) of any project which will demonstrate a new or improved method, approach, or technology for providing a dependably safe supply of drinking water to the public; and

(2) assisting in the development and demonstration (including construction) of any project which will investigate and demonstrate health and conservation implications involved in the reclamation, recycling, and reuse of wastewaters for drinking and the processes and methods for the preparation of safe and acceptable drinking water.

Grants, limitations.

(b) Grants made by the Administrator under this section shall be subject to the following limitations:

(1) Grants under this section shall not exceed 66⅔ per centum of the total cost of construction of any facility and 75 per centum of any other costs, as determined by the Administrator.

(2) Grants under this section shall not be made for any project involving the construction or modification of any facilities for any public water system in a State unless such project has been approved by the State agency charged with the responsibility for safety of drinking water (or if there is no such agency in a State, by the State health authority).

(3) Grants under this section shall not be made for any project unless the Administrator determines, after consultation, that such project will serve a useful purpose relating to the development and demonstration of new or improved techniques, methods, or technologies for the provision of safe water to the public for drinking.

(c) There are authorized to be appropriated for the purposes of this section $25,000,000 for fiscal year 1978.

Research and development program.
42 USC 4363.

SEC. 6. (a) The Administrator of the Environmental Protection Agency shall establish a separately identified program to conduct continuing and long-term environmental research and development. Unless otherwise specified by law, at least 15 per centum of any funds appropriated to the Administrator for environmental research and development under section 2(a) of this Act or under any other Act shall be allocated for long-term environmental research and development under this section.

Report to President and Congress.

(b) The Administrator, after consultation with the Science Advisory Board, shall submit to the President and the Congress a report concerning the desirability and feasibility of establishing a national environmental laboratory, or a system of such laboratories, to assume or supplement the long-term environmental research functions created by subsection (a) of this section. Such report shall be submitted on or before March 31, 1978, and shall include findings and recommendations concerning—

Contents.

(1) specific types of research to be carried out by such laboratory or laboratories;

(2) the coordination and integration of research to be conducted by such laboratory or laboratories with research conducted by existing Federal or other research facilities;

(3) methods for assuring continuing long-range funding for such laboratory or laboratories; and

(4) other administrative or legislative actions necessary to facilitate the establishment of such laboratory or laboratories.

42 USC 4364.

SEC. 7. (a) The Administrator of the Environmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or any other provision of law for environmental research and development related to regulatory program activities shall be coordinated with and reflect the research needs and priorities of the program offices, as well as the overall research needs and priorities of the Agency, including those defined in the five-year research plan.

Program offices.

(b) For purposes of subsection (a), the appropriate program offices are—

(1) the Office of Air and Waste Management, for air quality activities;

(2) the Office of Water and Hazardous Materials, for water quality activities and water supply activities;

(3) the Office of Pesticides, for environmental effects of pesticides;

(4) the Office of Solid Waste, for solid waste activities;

(5) the Office of Toxic Substances, for toxic substance activities;

(6) the Office of Radiation Programs, for radiation activities; and

(7) the Office of Noise Abatement and Control, for noise activities.

Report to President and Congress.

(c) The Administrator shall submit to the President and the Congress a report concerning the most appropriate means of assuring, on a continuing basis, that the research efforts of the Agency reflect the needs and priorities of the regulatory program offices, while maintaining a high level of scientific quality. Such report shall be submitted on or before March 31, 1978.

Science Advisory Board. Establishment. 42 USC 4365.

SEC. 8. (a) The Administrator of the Environmental Protection Agency shall establish a Science Advisory Board which shall provide such scientific advice as the Administrator requests.

Membership.

(b) Such Board shall be composed of at least nine members, one of whom shall be designated Chairman, and shall meet at such times and places as may be designated by the Chairman of the Board in consultation with the Administrator. Each member of the Board shall be qualified by education, training, and experience to evaluate scientific and technical information on matters referred to the Board under this section.

42 USC 4361.

(c) In addition to providing scientific advice when requested by the Administrator under subsection (a), the Board shall review and comment on the Administration's five-year plan for environmental research, development, and demonstration provided for by section 5 of Public Law 94-475 and on each annual revision thereof. Such review and comment shall be transmitted to the Congress by the Administrator, together with his comments thereon, at the time of the transmission to the Congress of the annual revision involved.

Report to Administrator, President, and Congress.

(d) The Board shall conduct a review of and submit a report to the Administrator, the President, and the Congress, not later than October 1, 1978, concerning—

(1) the health effects research authorized by this Act and other laws;

(2) the procedures generally used in the conduct of such research;

(3) the internal and external reporting of the results of such research;

(4) the review procedures for such research and results;

(5) the procedures by which such results are used in internal and external recommendations on policy, regulations, and legislation; and

(6) the findings and recommendations of the report to the House Committee on Science and Technology entitled "The

Environmental Protection Agency's Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report".

The review shall focus special attention on the procedural safeguards required to preserve the scientific integrity of such research and to insure reporting and use of the results of such research in subsequent recommendations. The report shall include specific recommendations on the results of the review to ensure scientific integrity throughout the Agency's health effects research, review, reporting, and recommendation process.

(e)(1) The Administrator, at the time any proposed criteria document, standard, limitation, or regulation under the Clean Air Act, the Federal Water Pollution Control Act, the Resource, Conservation and Recovery Act of 1976, the Noise Control Act, the Toxic Substances Control Act, or the Safe Drinking Water Act, or under any other authority of the Administrator, is provided to any other Federal agency for formal review and comment, shall make available to the Board such proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the Environmental Protection Agency on which the proposed action is based.

42 USC 1857 note.
33 USC 1251 note.
42 USC 6901 note.
42 USC 4901 note.
15 USC 2601 note.
42 USC 300f note.

(2) The Board may make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed criteria document, standard, limitation, or regulation, together with any pertinent information in the Board's possession.

(f) In preparing such advice and comments, the Board shall avail itself of the technical and scientific capabilities of any Federal agency, including the Environmental Protection Agency and any national environmental laboratories.

Member committees and investigative panels.

(g) The Board is authorized to constitute such member committees and investigative panels as the Administrator and the Board find necessary to carry out this section. Each such member committee or investigative panel shall be chaired by a member of the Board.

Secretary, appointment.

(h)(1) Upon the recommendation of the Board, the Administrator shall appoint a secretary, and such other employees as deemed necessary to exercise and fulfill the Board's powers and responsibilities. The compensation of all employees appointed under this paragraph shall be fixed in accordance with chapter 51 and subchapter III of chapter 53 of title 5 of the United States Code.

5 USC 5101, 5331.

(2) Members of the Board may be compensated at a rate to be fixed by the President but not in excess of the maximum rate of pay for grade GS-18, as provided in the General Schedule under section 5332 of title 5 of the United States Code.

5 USC 5332 note

(i) In carrying out the functions assigned by this section, the Board shall consult and coordinate its activities with the Scientific Advisory Panel established by the Administrator pursuant to section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

7 USC 136w.
42 USC 4366.

SEC. 9. (a) The Administrator of the Environmental Protection Agency, in consultation and cooperation with the heads of other Federal agencies, shall take such actions on a continuing basis as may be necessary or appropriate—

(1) to identify environmental research, development, and demonstration activities, within and outside the Federal Govern-

ment, which may need to be more effectively coordinated in order to minimize unnecessary duplication of programs, projects, and research facilities;

(2) to determine the steps which might be taken under existing law, by him and by the heads of such other agencies, to accomplish or promote such coordination, and to provide for or encourage the taking of such steps; and

(3) to determine the additional legislative actions which would be needed to assure such coordination to the maximum extent possible.

Report.
42 USC 4361.

The Administrator shall include in each annual revision of the five-year plan provided for by section 5 of Public Law 94–475 a full and complete report on the actions taken and determinations made during the preceding year under this subsection, and may submit interim reports on such actions and determinations at such other times as he deems appropriate.

(b) The Administrator of the Environmental Protection Agency shall coordinate environmental research, development, and demonstration programs of such Agency with the heads of other Federal agencies in order to minimize unnecessary duplication of programs, projects, and research facilities.

Report to President and Congress.
Legislative recommendations.

(c)(1) In order to promote the coordination of environmental research and development activities, and to assure that the action taken and methods used (under subsection (a) and otherwise) to bring about such coordination will be as effective as possible for that purpose, the Council on Environmental Quality in consultation with the Office of Science and Technology Policy shall promptly undertake and carry out a joint study of all aspects of the coordination of environmental research and development. The Chairman of the Council shall prepare a report on the results of such study, together with such recommendations (including legislative recommendations) as he deems appropriate, and shall submit such report to the President and the Congress not later than May 31, 1978.

Presidential report to Congress.

(2) Not later than September 30, 1978, the President shall report to the Congress on steps he has taken to implement the recommendations included in the report under paragraph (1), including any recommendations he may have for legislation.

42 USC 4361b.

Sec. 10. The Administrator of the Environmental Protection Agency shall implement the recommendations of the report prepared for the House Committee on Science and Technology entitled "The Environmental Protection Agency Research Program with primary emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report", unless for any specific recommendation he determines (1) that such recommendation has been implemented, (2) that implementation of such recommendation would not enhance the quality of the research, or (3) that implementation of such recommendation will require funding which is not available. Where such funding is not available, the Administrator shall request the required authorization or appropriation for such implementation. The Administrator shall report the status of such implementation in each annual revision of the five-year plan transmitted to the Congress under section 5 of Public Law 94–475.

Personnel positions, increase.

Sec. 11. The Administrator of the Environmental Protection Agency shall increase the number of personnel positions in the Health and Ecological Effects program to 862 positions for fiscal year 1978.

Annual statement, filing. 42 USC 4367.

Sec. 12. (a) Each officer or employee of the Environmental Protection Agency who—

(1) performs any function or duty under this Act; and

(2) has any known financial interest in any person who applies for or receives grants, contracts, or other forms of financial assistance under this Act,

shall, beginning on February 1, 1978, annually file with the Administrator a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be available to the public.

(b) The Administrator shall—

(1) act within ninety days after the date of enactment of this Act—

(A) to define the term "known financial interest" for purposes of subsection (a) of this section; and

(B) to establish the methods by which the requirement to file written statements specified in subsection (a) of this section will be monitored and enforced, including appropriate provision for the filing by such officers and employees of such statements and the review by the Administrator of such statements; and

Report to Congress.

(2) report to the Congress on June 1 of each calendar year with respect to such disclosures and the actions taken in regard thereto during the preceding calendar year.

(c) In the rules prescribed under subsection (b) of this section, the Administrator may identify specific positions of a nonpolicymaking nature within the Administration and provide that officers or employees occupying such positions shall be exempt from the requirements of this section.

Violation, penalty.

(d) Any officer or employee who is subject to, and knowingly violates, this section, shall be fined not more than $2,500 or imprisoned not more than one year, or both.

Paperwork minimization, encouragement.

Sec. 13. It is the national policy that to the maximum extent possible the procedures utilized for implementation of this Act shall encourage the drastic minimization of paperwork.

Approved November 8, 1977.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 95-157 (Comm. on Science and Technology) and No. 95-722 (Comm. of Conference).

SENATE REPORT No. 95-188 accompanying S. 1417 (Comm. on Environment and Public Works).

CONGRESSIONAL RECORD, Vol. 123 (1977):

Apr. 19, considered and passed House.
May 27, considered and passed Senate, amended, in lieu of S. 1417.
Oct. 20, Senate agreed to conference report.
Oct. 25, House agreed to conference report.

O

Appendix B

COMMITTEE MEMBERS AND CONSULTANTS

1. Subcommittee Core Members

Chairman: Dr. James L. Whittenberger
Professor of Physiology
School of Public Health
Harvard University

Co-chairman: Dr. Roger O. McClellan
Director of Inhalation Toxicology
Research Institute
Lovelace Foundation

Members: Dr. Peter Bloomfield
Associate Professor
Department of Statistics
Princeton University

Dr. George W. Comstock
Professor of Epidemiology
Johns Hopkins Training Center

Dr. Morton Corn
Professor of Industrial Health and
Air Engineering
Graduate School of Public Health
University of Pittsburgh

Dr. Julius E. Johnson
Consultant
Dow Chemical Company

Dr. Wendell Kilgore
Professor of Toxicology
Department of Environmental
Toxicology
University of California at Davis

Dr. Robert A. Neal
Director, Center in Toxicology
Department of Biochemistry
Vanderbilt Medical School

Dr. Gerard A. Rohlich
Professor of Environmental
Engineering, Department of Civil
Engineering, University of Texas

SAB Staff Officer: Dr. Frode Ulvedal
Supervisory Toxicologist
Office of Research and Development
Environmental Protection Agency

2. Consultants

Dr. Edwin Lennette, Biomedical Labs, California State Department of Health
expertise: microbiology, virology

Dr. Jeanne Manson, Kettering Laboratory
University of Cincinnati
expertise: reproduction,teratology

Dr. Sol M. Michaelson, Professor of Radiation Biology and Biophysics, University of Rochester
expertise: non-ionizing radiation

Dr. Steven M. Horvath, Director, Institute of Environmental Stress, University of California
expertise: pulmonary physiology, inhalation toxicology

Dr. George Hutchinson, Professor of Epidemiology, Harvard School of Public Health
expertise: epidemiology, microbiology

Dr. James G. Fox, Director, Laboratory of Animal Medicine, Massachusetts Institute of Technology
expertise: laboratory animal care and facilities

Dr. Jennifer L. Kelsey, Associate Professor of Epidemiology, Department of Epidemiology and Public Health, Yale University School of Medicine
expertise: epidemiology of chronic disease

Dr. Ralph C. Buncher, University of Cincinnati Medical Center
expertise: epidemiology

APPENDIX C

MEETING AND TRAVEL SCHEDULE FOR HERRG

DATE	LOCATION	PARTICIPANTS
21 June 78	Preliminary meeting, with Dr. Hueter, HERL/RTP	Dr. Whittenberger Dr. Ulvedal
13-14 July 78	Public meeting, Washington, D.C.	HERRG
20-21 July 78	Environmental Research Lab Duluth, Minn.	Dr. McClellan Dr. Kilgore Dr. Ulvedal
23 Aug. 78	Office of Water & Waste Management Washington, D.C.	Dr. Rohlich Dr. Neal Dr. Johnson Dr. Ulvedal
25 Aug 78	Office of Toxic Substances Washington, D.C.	Dr. Neal Dr. Kilgore Dr. Johnson Dr. Ulvedal
25-27 Sept. 78	Health Effects Research Lab Research Triangle Park, N.C.	HERRG and Dr. Manson Dr. Michaelson Dr. Horvath Dr. Hutchinson Dr. Fox Dr. Kelsey Dr. Ulvedal
28 Sept. 78	Preliminary Mtg. with Dr. Garner HERL/Cincinnati	Dr. McClellan Dr. Ulvedal
5-6 Oct. 78	Environmental Research Lab Gulf Breeze, Fla.	Dr. Whittenberger Dr. Kilgore Dr. Ulvedal
16-18 Oct. 78	Health Effects Research Lab Cincinnati, Ohio	HERRG and Dr. Lennette Dr. Hutchinson Dr. Fox Dr. Buncher
19 Oct. 1978	Health Effects Research Lab. Field Station Wenatchee, Wash.	Dr. McClellan Dr. Johnson Dr. Kilgore Dr. Ulvedal

DATE	LOCATION	PARTICIPANTS
24 Oct. 78	Office of Air, Noise, & Radiation	Dr. Whittenberger Dr. Corn Dr. Bloomfield Dr. Ulvedal
26 Oct. 78	Environmental Research Lab. Narragansett, R.I.	Dr. Whittenberger Dr. Lennette Dr. Ulvedal
27 Oct. 78	Health Effects Research Lab Field Station W. Kingston, R.I.	Dr. Whittenberger Dr. Lennette Dr. Ulvedal
30 Oct. 78	Office of Planning and Management Washington, D.C.	Dr. McClellan Dr. Ulvedal
8 Nov. 78	Region I Boston, Mass.	Dr. Whittenberger Dr. Ulvedal
9 Nov. 78	Environmental Monitoring & Support Laboratory, Las Vegas, Nev.	Dr. McClellan Dr. Ulvedal
13-14 Nov. 78	Public Meeting Washington, D.C.	HERRG
13 Nov. 78	Office of Planning and Management Washington, D.C.	Dr. Corn Dr. McClellan Dr. Johnson Dr. Bloomfield
13 Nov. 78	Office of Research and Development Washington, D.C.	Dr. Whittenberger Dr. Kilgore Dr. Neal

APPENDIX D

PRINCIPAL EPA PERSONNEL PROVIDING INFORMATION TO HERRG

* Interviewed
+ Provided written information

Office of the Administrator

Douglas M. Costle*+
Administrator

Dr. Richard Dowd*
Science Policy Advisor to the Administrator
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federal register

THURSDAY, NOVEMBER 30, 1978
PART II

THE NATIONAL ARCHIVES OF THE UNITED STATES
1934

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

EPA

REGULATORY AGENDA

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 983-5]

AGENDA OF REGULATIONS

AGENCY: Environmental Protection Agency.

ACTION: Agenda of Regulations.

SUMMARY: Four times a year the Agency publishes a summary of the significant regulatory actions under development to help assure that interested parties have an early opportunity to participate in shaping our regulations. We call the summary our Agenda of Regulations.

FOR FURTHER INFORMATION CONTACT: For information about any particular item on the Agenda contact the individual identified as the contact person for that item. For general information about public participation in the regulatory process contact:

Chris Kirtz, (PM-223), Standards and Regulations Evaluation Division, Environmental Protection Agency, 401 M Street, SW Washington, D.C. 20460.

SUPPLEMENTARY INFORMATION: On March 23, 1978, President Carter signed Executive Order 12044, *Improving Government Regulations*, which directed all executive agencies to adopt procedures to improve existing and future regulations. One procedure which the Order required all agencies to adopt was the publication twice a year of a list of significant regulations which are under development or review. The Order also directed that the Agenda provide the following information about the potential regulations:

- A brief description
- A citation of its statutory authority
- Its status
- The name and phone number of a knowledgeable official
- Whether we will prepare a regulatory analysis due to the regulation's potentially major economic consequences
- Whether the listed item is an existing regulation which we are reevaluating

The Order also directed that the Agenda provide the status of all items listed on the previous Agenda.

EPA's previous Regulatory Agenda was published April 6, 1978.

COVERAGE

We have tried to list all significant actions which are going through the Agency's formal regulation development process, but we may have inadvertently omitted a few. Appearance or nonappearance in the Agenda carries with it no legal significance.

Executive Order 12044 gave general guidelines on determining what regulations were significant and which, therefore, should be included on the Agenda. It directed each agency to develop specific criteria for identifying significant regulations. We will describe our criteria for determining significant regulations in our final report responding to the Executive Order. I will be signing this report soon, and you will be able to obtain copies of it from Philip Schwartz (PM-223), Washington, D.C., 20460.

The Agency's formal process of regulation development starts when an Assistance Administrator sends a notice form to the Administrator and other senior management. This form notifies all EPA offices that a regulation is about to be prepared and allows these offices to plan their participation.

Different events might trigger the start of the Agency's formal regulation development process. The most common event is the passage of new legislation. Other common triggers include new scientific studies; advances in technology; petitions for rulemaking sent in from outside EPA; judicial documents such as court orders and consent agreements; and simply, operating experience with a particular regulation which may suggest ways that we can improve it.

EXPLANATION OF INFORMATION IN THE AGENDA

The Agenda lists prospective regulatory actions authorized by the following laws:

- the Clean Air Act (CAA)
- the Motor Vehicle Information and Cost Savings Act (MVICSA)
- the Safe Drinking Water Act (SDWA)
- the Noise Control Act (NCA)
- the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- the Atomic Energy Act (AEA)
- the Public Health Service Act (PHSA)
- the Resource Conservation and Recovery Act (RCRA)
- the Toxic Substances Control Act (TSCA)
- the Federal Water Pollution Control Act as amended by the Clean Water Act (CWA)

The first column of the Agenda provides the following information about each regulation:

- A citation from the Code of Federal Regulations
- A short title
- A citation of statutory authority
- A description, including whether the item is an existing regulation which we are reevaluating

If the regulation may have economic consequences large enough to require a regulatory analysis, an asterisk (*) appears at the beginning of the entry.

The second column lists the date we proposed a regulation in the FEDERAL REGISTER or the month in which we expect to propose it.

The third column lists the date we published a final regulation or the month in which we expect to publish the final regulation.

The fourth column provides the name, address, and phone number of whom to contact for each regulation.

DOUGLAS M. COSTLE,
Administrator.

NOVEMBER 20, 1978.

MAJOR EPA REGULATIONS UNDER CONSIDERATION

<table>
<tr><th>Name and description of regulation</th><th>Proposal date in FEDERAL REGISTER</th><th>Final date in FEDERAL REGISTER</th><th>Contact person and address</th></tr>
<tr><td colspan="4">THE CLEAN AIR ACT</td></tr>
<tr><td colspan="4">We are developing the following seven items under the authority of secs. 108 and 109 of the CAA which direct the Administrator to establish national Ambient Air Quality Standards (NAAQS). To write a NAAQS for any pollutant, we first prepare a criteria document which contains the latest scientific knowledge on the kind and extent of public health and welfare problems caused by the presence of the pollutant in the air. If we revise the criteria document, we may find it necessary to also change the NAAQS.
A National Primary Ambient Air Quality Standard defines the Maximum amount of an air pollutant which the Administrator of EPA determines is compatible with an adequate margin of safety to protect the public health. A National Secondary Ambient Air Quality Standard defines levels of air quality which the Administrator judges necessary to protect the public welfare from any known or anticipated adverse effects of a pollutant.</td></tr>
<tr><td>40 CFR 50 *Review of NAAQS for Photochemical Oxidants. CAA 108. The proposed regulation would change the existing primary, health-based standard to 0.10 ppm for a 1-hour average from the existing 0.08 ppm standard. The secondary, welfare-based standard would remain at 0.08 ppm for 1-hour average. The pollutant we control would be changed from photochemical oxidants to ozone, which is the principal measurable ingredient in photochemical oxidants.</td><td>June 22, 1978</td><td>December 1978</td><td>Joe Padgett (MD-12), Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5204, FTS 8-629-5204.</td></tr>
</table>

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in Federal Register	Final date in Federal Register	Contact person and address
The Clean Air Act			
40 CFR 50 **NAAQS for Lead.* CAA 108. EPA proposed an ambient lead standard of 1.5 micrograms per cubic meter averaged over 30 days. Public reaction has been mixed. Federal agencies and public interest groups support the proposal. Industry argues that: (1) the health data and analyses do not support the standard, (2) large parts of the secondary lead and foundry industries are *Technically* unable to comply, and (3) plant closures for economic and technical reasons will result from enforcement of the standard.	Dec. 14, 1977	Oct. 5, 1978	Do.
40 CFR 50 **Review of NAAQS for Carbon Monoxide.* CAA 108. The health basis for control of this pollutant will we reviewed. This requires preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	September 1979	February 1980	Do.
40 CFR 50 **Review of NAAQS for Sulfur Oxides.* CAA 108. A review of the health basis for control of this pollutant will require preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	May 1980	December 1980	Do.
40 CFR 50 **Review of Long Term NAAQS for Nitrogen Dioxide* CAA 108. The NAAQS for nitrogen dioxide is undergoing review. ORD will complete a revised criteria document by January 1979. Under the CAA amendments, the criteria and the decision to revise the standard must address both the long-term effects of NO2, and effects associated with other nitrogen species in the air, particularly nitrates, and nitric acid aerosol.	January 1979	June 1979	Do.
40 CFR 50 **Review of NAAQS for Particulates.* CAA 108. A review of the health basis for control of this pollutant will require preparation of an updated criteria document and analysis of whether or not NAAQS should be revised.	May 1980	December 1980	Do.
40 CFR 50 **Development of Short Term NAAQS for Nitrogen Dioxide.* CAA 109. The Clean Air Act Amendments of 1977 require proposal and promulgation of a 1-3 hour standard for NO2 unless EPA finds that such a standard is not necessary to protect the public health.	January 1979	June 1979	Do.
We are developing performance standards to control emissions from the following industries under sec. 111(b) of the CAA. This section requires that the Administrator develop New Source Performance Standards (NSPS) for stationary sources which significantly contribute to air pollution. The NSPS are based on the best system of continuous emission reduction which has been adequately demonstrated. The standards would apply to both new sources and existing sources which are modified after approval of the regulation.			
40 CFR 60 **NSPS—Fossil Fuel Steam Generators (Revision).* CAA 111. Revised standards are being proposed for utility boilers for control of SO2, NOx and particulates. The revised NSPS will apply to any fossil-fueled utility boiler with a heat input of 250 million Btu/hour or greater. The NSPS will require a percent removal of sulfur dioxide and will include an emission ceiling and an emission floor.	Sept. 19, 1978	March 1979	Don Goodwin (MD-13). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5271, FTS 8-629-5271.
40 CFR 60 *NSPS—Petroleum Liquid Storage Vessels.* CAA 111. This is a revision of 1974 NSPS. The revised standard will propose the use of double seals rather than single seals on floating roofs. The standard, as currently being developed, will essentially eliminate one of two types of seals currently in use.	May 18, 1978	do	Do.
40 CFR 60 *NSPS—Glass Manufacturing.* CAA 111. This regulation will address the problem of emissions from new glass manufacturing furnaces. The Governor of New Jersey requested that EPA develop national standards.	February 1979	December 1979	Do.
40 CFR 60 *NSPS—Internal Combustion Engines.* CAA 111. These regulations will require the application of best demonstrated control technology to control emissions from stationary internal combustion engines. It will also require States to act under sec. 111(d) to regulate these compounds from existing sources.	December 1978	do	Do.
40 CFR 60 *NSPS—Sulfur Recovery in Natural Gas Fields.* CAA 111. This regulation will control emissions of total reduced sulfur compounds.	July 1979	May 1980	Do.
40 CFR 60 *NSPS—Non-Metallic Minerals.* CAA 111. Particulate emissions from quarrying operations and related facilities will be controlled.	January 1979	December 1979	Do.
40 CFR 60 *NSPS—Organic Solvent Metal Cleaning.* CAA 111. This rule will control evaporative emissions from metal cleaning and degreasing operations.	March 1979	January 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 60 *NSPS—Surface Coating Operations for Auto Assembly Plants.* CAA 111. Evaporative emissions from coating operations in the auto and light truck industry will be controlled.	February 1979	......do	Do.
40 CFR 60 *NSPS—Synthetic Organic Chemical manufacturing.* CAA 111. Selection of a degree of control of emission from manufacture of over 100 major organic chemicals is to be made. A series of standards will be proposed.	March 1979	......do	Do.
40 CFR 60 *NSPS—Can Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from can coating operations.	November 1979	September 1980	Do.
40 CFR 60 *NSPS—Pressure Sensitive Tapes and Labels Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from pressure sensitive tapes and label operations.	January 1980	November 1980	Do.
40 CFR 60 *NSPS—Metal Furniture Surface Coating.* CAA 111. This regulation will establish emission standards for volatile organic emissions from metal furniture operations.	December 1978	December 1979	Do.
40 CFR 60 *NSPS—Lead Battery Manufacturing.* CAA 111. This regulation will establish emission standards for lead and sulfuric acid mist emissions from lead battery manufacturing facilities. The action on H2S04 will key the requirement that States regulate existing sources under sec. 111(d).	April 1979	February 1980	Do.
40 CFR 60 *NSPS—Gas Turbines.* CAA 111. This regulation will establish limitations on oxide of nitrogen emissions from stationary gas turbines.	Oct. 3, 1977	February 1979	Do.
40 CFR 60 *NSPS—Industrial Boilers.* CAA 111. This regulation will control the emissions of particulates, NOx and SO2.	October 1980	August 1981	Do.
40 CFR 60 *NSPS—Phosphate Rock.* CAA 111. This regulation will control the emission of particulates.	May 1979	March 1980	Do.
40 CFR 60 *Aluminum Plant Flouride Control—Existing Plants.* CAA 111(d). These are guidelines for State control of flouride emissions from existing aluminum plants.	January 1979	November 1979	Do.
40 CFR 60 *Guidelines for Existing Kraft Pulp Mills.* CAA 111(d). These are guidelines to control sulfur (odors) from existing Kraft pulp mills will allow States flexibility in establishing controls.	Feb. 23, 1978	January 1979	Do.
40 CFR 60 *List of New Source Performance Standards.* CAA 111(f). The 1977 Clean Air Act requires the Administrator to list the categories of major stationary sources that are not already controlled by NSPS. He must then issue standards for these categories within 4 years.	Aug. 31, 1978	May 1979	Do.
We are developing emission standards for hazardous air pollutants under sec. 112 of the CAA. This section requires that the Administrator develop National Emission Standards for Hazardous Air Pollutants (NESHAPS) for emissions which cause or contribute to air pollution which results in an increase in mortality, or an increase in serious or incapacitating illness. The standards would apply to both new sources and existing sources.			
40 CFR 61 *NESHAPS: Asbestos-Iron Ore Beneficiation.* CAA 112. This regulation would establish limits on asbestos emissions from iron ore beneficiation facilities.	September 1979	July 1980	Don Goodwin (MD-13). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5271, FTS 8-629-5271.
40 CFR 61 *NESHAPS: Vinyl Chloride Amendments.* CAA 112. The proposed regulations have called for increased control of existing sources, stringent control of new sources, and a zero emission goal.	June 7,1977	Indeterminate	Do.
40 CFR 61 *NESHAPS: Handling and Storage.* CAA 112. This regulation would control the handling and storage of benzene and benzene-rich liquids.	August 1979	June 1980	Do.
40 CFR 61 *NESHAPS: Gasoline Distribution Systems.* CAA 112. This regulation would control benzene emissions from major marketing sources such as bulk terminals, bulk plants, and service stations.	Indeterminate	Indeterminate	Do.
40CFR 61 *NESHAPS—Refinery Sources.* CAA 112. This regulation would control the emission of benzene from point sources as well as from fugitive sources (pumps, valves, etc.) and waste disposal.	September 1979	November 1980	Do.
40 CFR 61 *NESHAPS—Maleic Anhydride.* CAA 112. This regulation would control the emission of benzene in the manufacture of maleic anhydride.	January 1979	November 1979	Do.
40 CFR 61 *NESHAPS—Ethyl Benzene.* CAA 112. This regulation would control the emission of benzene in the manufacture of ethyl benzene.	March 1979	January 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 61 *NESHAPS—Styrene.* CAA 112. This regulation would control the emission of benzene in the manufacture of styrene.	June 1979	April 1980	Do.
40 CFR 61 *NESHAPS: Asbestos Released from Crushed Stone.* CAA 112. Use of crushed serpentine rock for roadway surfacing may release significant quantities of asbestos. A monitoring program is under way and results indicate standards will be proposed.	May 1980	March 1981	Do.
40 CFR 61 *NESHAPS: Coke Oven Emission-Charging Operations.* CAA 112. The regulation would define coke oven emissions as a hazardous air pollutant. Charging operations would be regulated first. Regulations on top side leaks would follow.	December 1978	September 1979	Do.
40 CFR 61 *NESHAPS: Arsenic.* CAA 112. A health risk assessment is being conducted. If i is determined that arsenic emissions (primarily from copper smelters) are a hazardous air pollutant, then emission standards would be proposed.	December 1979		Joe Padgett (MD-12). Environmental Protection Agency, Research Triangle Park, N.C. 27711 919-541-5204, FTS 8-629-5204.
40 CFR 57 *Primary Nonferrous Smelter Orders.* CAA 119. These regulations will establish the substantive requirements of initial primary nonferrous smelter orders (NSO's) and the procedures to be used in issuing them. NSO's will allow certain copper, lead, and zinc smelters to delay compliance with the requirements for constant control of sulfur dioxide emissions and let them use tall stacks and supplementary control systems to meet ambient standards.	December 1978	April 1979	Judith Larsen (EN-341). Environmental Protection Agency, Washington, D.C. 20460, 202-755-2583.
40 CFR 56 *Noncompliance Penalties.* CAA 120. EPA is required to establish a penalty program to start collecting money from polluters after mid-1979 in an amount equal to the money the polluter saves by failing to obey the law.	......do	Undetermined	Bob Homiak (EN-341). Environmental Protection Agency, Washington, D.C. 20460, 202-755-2542.
40 CFR 51 *Tall Stack Regulation.* CAA 123. The regulations will specify what height stacks may be given credit for dispersion under State implementation plans.	November 1978	April 1979	Dick Rhoads (MD-15). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5251, FTS 8-629-5251.
40 CFR 51.240 *Regulations Providing for State/Local Consultation.* CAA 121. The regulations will ask the States to provide a satisfactory process of consultation with local governments, elected officials, and Federal land managers. The regulations will also require the States to choose a lead planning organization to coordinate the State Implementation Plan revisions for oxidants (smog) and carbon monoxide.	May 18, 1978	December 1978	John Hidinger (AW-445). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0481.
1979 Listing of Radioactive Pollutants. CAA 122. Determine whether radioactive pollutants shall be classified as 108, 111, or 112 pollutants or none of these categories.	August 1980	Undetermined	William A. Mills (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-0704.
40 CFR 51 *Emission Offset Policy Regulations.* CAA 129. These regulations address the issue of whether and to what extent the national ambient air quality standards established under CAA restrict or prohibit growth of major new or expanded air pollution sources. These proposed revisions reflect the public comments (including four public hearings on the December 21 ruling and the changes required by CAA Amendments of 1977).	Dec. 21, 1976	November 1978	Kent Berry (MD-11). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5343, FTS 8-629-5343.
40 CFR 51 and 52 *Prevention of Significant Deterioration (PSD).* Set II. CAA 166. These regulations will insure that areas which are in compliance with hydrocarbon, carbon monoxide, photochemical oxidant, and nitrogen oxide standards will remain in compliance.	December 1979	October 1980	Dick Rhoads (MD-15). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5251, FTS 8-629-5251.
Visibility Protection. CAA 167(a). EPA is required to prepare a report to Congress and guidelines which require SIP's to address visibility problems.	October 1979	August 1980	Joe Padgett. Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5204, FTS 8-629-5204.
40 CFR 85 *Requirements to Build Demonstration Cars Meeting 0.4 Gram/Mile NOx Standard.* CAA 202. All manufacturers with a least a 0.5 pct share of the U.S. passenger car market will have to build research vehicles which meet the 0.4 grams nitrogen dioxide per mile research objective. This regulation will be published in interim-final form.	December 1978	July 1979	Karl Hellman. Emission Control Technology Division, Environmental Protection Agency, 2565 Plymouth Rd., Ann Arbor, Mich. 48105, 313-668-4246.
40 CFR 86 *Light-Duty Diesel Particulate Standards.* CAA 202. EPA is required to set particulate standards for mobile sources starting in 1981. The regulation will contain 1981 standards and more stringent standards for 1983 and later model years.	......do	July 1979	Merrill Korth. Emission Control Technology Division, Environmental Protection Agency, 2565 Plymouth Rd., Ann Arbor, Mich. 48105, 313-668-4299.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 86 *Heavy-Duty Diesel Particulate Standards*. CAA 202. Although required by CAA for 1981 models, there is no test procedure available that can be used as the basis for a standard. A 1983 model year is targeted.	December 1980	August 1980	Do.
40 CFR 86 *Test Procedures for Measuring Heavy Duty Evaporative Emissions*. CAA 202(a). The Clean Air Act requires that a test procedure be promulgated which will require measurement of evaporative emission from the vehicles as a whole. EPA will promulgate test procedure and standards.	December 1978	August 1980	**Mike Leiferman.** **Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4271.**
40 CFR 86 *Heavy-Duty Evaporative Emission Standards*. CAA 202(a). Standards will apply to heavy-duty gasoline vehicles and will control emissions due to evaporation of gasoline beginning in model year 1981.	January 1979	August 1980	Do.
40 CFR 86 *Light Duty Truck Emission Standards (Up to 8500 lbs. Gross Vehicle Weight Rating—GVWR)*. CAA 202(a). CAA requires standards for 6,000-8,500 lb trucks that represent a 90 percent reduction in HC and CO from baseline for 1983. Standards are expected to be equivalent in stringency to 1981 passenger car standards and are expected 1 year ahead of CAA deadline, i.e. 1982 model year. The same standards will also be applied to trucks under 6,000 lb GVWR.	do	August 1979	**William Houtmann.** **Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4272.**
40 CFR 86 *HC and CO Emission Standards for Heavy Duty Vehicles (Over 8,500 Pounds)*. CAA 202(a)(3). The CAA requires EPA to establish emission standards for engines for heavy-duty vehicles over 8,500 pounds. Standards for HC and CO are a 90 percent reduction from baseline emissions for 1983 model year. EPA is in the process of developing a new test procedure for measuring exhaust emissions and measurements of baseline emissions.	December 1978	December 1979	**Chet France.** **Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4338.**
40 CFR 86 *NOx Emission Standard for Heavy Duty Vehicles (Over 8,500 Pounds)*. CAA 202(a)(3). The CAA requires EPA to establish emission standards for heavy-duty vehicles (over 6,000 lbs. GVWR). A 75 percent reduction for NOx beginning with 1985 model year. EPA is in the process of developing a new test procedure for measuring exhaust emissions and must then measure baseline emissions.	December 1979	September 1980	Do.
Fill Pipe Standards. CAA 202(a)(5). At such time as phase II vapor recovery regulations are promulgated, EPA is required to set standards for vehicle refueling orifices and associated parts of the fuel system to provide effective connection between the fill pipe and vapor recovery refueling nozzles. The effective model is to be determined on the basis of lead time required for design and production of the required systems. The type of fill pipe needed depends of whether phase II or on-board HC control is selected by EPA.	September 1979	June 1980	**Ernie Rosenberg (AW-455).** **Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.**
On-Board Hydrocarbon Technology. CAA 202(a)(6). Under this section EPA is required to determine whether onboard HC controls are feasible and more desirable than Phase II: Vapor Recovery, taking into consideration such factors as fuel economy, costs, admininstrative burdens, equitable distribution of costs and safety. If found feasible and desirable, onboard HC control standards are to be set by EPA, with such lead time as is needed for implementation. In issuing such regulations, EPA is required to consult with the Department of Transportation regarding the safety of the controls.	September 1979	June 1980	**Paul Stolpman (AW-443).** **Environmental Protection Agency, Washington, D.C. 20460, 202-426-2484.**
40 CFR 86 *Interim High Altitude Requirements*. CAA 202(a), (f). The regulations will set requirements for car to meet the standards at high altitude for 1981-83.	December 1978	August 1979	**William Houtmann.** **Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4272.**
40 CFR 85 *Importation of Motor Vehicles and Motor Vehicle Engines*. CAA 203. The regulation attempts to improve the effectiveness and administration of EPA's program to prevent importation of vehicles and engines which fail to conform to Federal emission standards.	December 1978	July 1979	**Tom Preston (EN-340).** **Environmental Protection Agency, Washington, D.C. 20460, 202-755-0944.**
40 CFR 86 *Regulations Defining Certificate of Conformity*. CAA 206(a). The regulations will identify the components and specifications that are a required part of motor vehicle certification; the parameters of allowable deviation of parts; and the specifications for the certification tests.	Dec. 23, 1974	March 1979	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN AIR ACT			
40 CFR 86 *Selective Enforcement Auditing of Motorcycles.* CAA 206(b). The regulation will establish a program for testing motorcycles at the assembly line to assure compliance with emission standards.	Holding		Frank Slaveter (EN-338). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Selective Enforcement Auditing of Heavy Duty Engines and Vehicles.* CAA 206(b). The regulation will establish a program for testing heavy duty engines and vehicles at the assembly line to assure compliance with emission standards.	December 1978	February 1979	Do.
40 CFR 86 *Engine Parameter Adjustment Regulations.* CAA 206(b). This regulation will limit the adjustment parameters of emissions-related controls on vehicles to ensure that after the vehicles pass certification tests, they are not readjusted in the field by dealerships or service stations to improve their driveability at the cost of increased emissions.	Oct. 21, 1977	November 1978	Ron Kruse. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4317.
40 CFR 86 *1984 High Altitude Standards.* CAA 206(f). These regulations will require all vehicles to meet standards at all altitudes beginning with 1984 models.	May 1981	May 1982	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Penalties for Noncomplying Heavy-Duty Engines and Vehicles.* CAA 206(g). This regulation would allow heavy-duty engine or vehicle manufacturers to sell vehicles or engines exceeding the standards if they pay a noncompliance penalty. They still would not be sold, however, if they exceed an upper limit.	December 1978	February 1979	Frank Slaveter (EN-338). Environmental Protection Agency, Washington, D.C. 20460, 202-755-1572.
40 CFR 86 *Emission Control Warranty.* CAA 207(a)(1). The regulations activate a manufacturer's warranty that becomes enforceable if the vehicle exceeds emission standards as a result of defects present at the time of sale.	December 1978	June 1979	Rick Friedman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4690.
40 CFR 86 *Aftermarket Parts Certification.* CAA 207(a)(2). The regulation establishes guidelines so aftermarket parts manufacturers can certify that their parts do not degrade emissions.	January 1979	August 1979	David Feldman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0297.
40 CFR 86 *Short Test for Emission Warranties.* CAA 207(b). The regulation establishes procedures for tests of emissions from light duty trucks and light duty vehicles to be performed in conjunction with inspection/maintenance programs.	May 25, 1977	January 1979	Dick Nash. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4412.
40 CFR 85 *Emission Control (Performance) Warranty.* CAA 207(b)(2). This regulation specifies performance warranty requirements based on short-cycled emissions test for in-use vehicles. It was proposed in May 1977 and is now being reproposed to take the Clean Air Act Amendments into account.	November 1978	April 1979	David Feldman (EN-340). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0297.
40 CFR 79.6 *Fuels and Fuel Additives Protocols for Testing.* CAA 211. The protocols will help determine effects of fuels and fuel additives on public health and emission control devices.	January 1979	May 1979	Matt Bills (RD-680). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4452.
40 CFR 86 *High Altitude Performance Adjustments.* CAA 215. EPA is required to set procedures by which manufacturers must have adjustments to their cars for high altitude operation approved.	February 1979	February 1980	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.
40 CFR 86 *Turbine Aircraft Gaseous Emissions Retrofit and Modification of 1973 Standards.* CAA 231. This regulation will propose, and for some classes of aircraft, repropose emission standards for large aircraft to reduce HC, NOx, and CO.	Mar. 24, 1978	September 1979	William Houtmann. Environmental Protection Agency, Ann Arbor, Mich. 48105, 313-668-4272.
40 CFR 56 *Regional Consistency.* CAA 301. EPA is required to provide for consistent implementation of the Clean Air Act by the various EPA Regional Offices.	January 1979	Undetermined	Darryl Tyler (MD-13). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5251, FTS 8-629-5425.
40 CFR 51, 52, 53, 58, and 60 *Monitoring Regulations.* CAA 319. These regulations will revise the requirements for State and local air pollution monitoring for purposes of State implementation plans and for reporting air quality data to EPA.	Aug. 7, 1978	January 1979	Robert Neligan (MD-14). Environmental Protection Agency, Research Triangle Park, N.C. 27711, 919-541-5447, FTS 8-629-5447.
THE MOTOR VEHICLE INFORMATION AND COST SAVINGS ACT (MVICSA)			
40 CFR 85 *Testing Retrofit Devices for Fuel Economy Performance.* MVICSA 511. The regulation provides for EPA evaluation of claims by a manufacturer that it has produced a fuel economy retrofit device.	Aug. 10, 1977	December 1978	Ernie Rosenberg (AW-455). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0596.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposed date in Federal Register	Final date in Federal Register	Contact person and address
THE CLEAN WATER ACT (Federal Water Pollution Control Act as amended by the Clean Water Act Amendments of 1977)			
40 CFR 35(P) *State Management Assistance.* CWA 101(b)/205. States may use up to 2 percent of their title II allotment or $400,000 whichever is greater, to finance the administration of sec. 201, 203, 208, 212, 402, and 404 programs.	Apr. 25, 1978, interim final	Sept. 27, 1978	Joe Ensley (WH-547). Environmental Protection Agency, Washington, D.C. 20460, 202-426-4445.
7 CFR 634 *Agricultural Cost Sharing.* CWA 208(j).). The Department of Agriculture will provide grants covering up to 59 percent of costs to install best management practices for water quality management. The program will be imple-by the USDA. The regulations will be promulgated by USDA with EPA concurrence.	June 22, 1978	To be determined	Joe Krivak (WH-585) Environmental Protection Agency, Washington, D.C. 20460, 202-755-7000.
40 CFR 35 *Water Quality Management Regulations.* CWA 106, 208, 303(e). These regulations revise and update the water quality management regulations previously issued under 40 CFR 130 and 131.	Sept. 12, 1978	January 1979	Linda Eichmiller (WH-554). Environmental Protection Agency, Washington, D.C. 20460, 202-755-6965.
40 CFR 35.15 *State 208 Regulatory Programs for Dredge and Fill Materials.* CWA 208(b)(4). These regulations will authorize States to establish regulatory programs for the discharge of dredge and fill material to supplement State 404 permit programs.	January 1979	July 1979	Joe Krivak. Environmental Protection Agency, Washington, D.C. 20460, 202-755-7000.
40 CFR 233 *Modification of Secondary Treatment Requirements for Marine Dischargers.* CWA 301(h). The 1977 amendments of the Clean water Act allow EPA to modify the treatment requirements for existing ocean dischargers from Publicly Own Treatment Works (POTW's) in regard to the required degree of removal of Biological Oxygen Demand (BOD), Total Suspended Solids (TSS), and pH. Applicants are required to meet eight specific 301(h) criteria in addition to any other applicable criteria of the Act. The receipt of modification would not relieve a POTW from compliance with performance standards which EPA will later publish to reflect Best Practicable Wastewater Treatment Technology (BPWTT). This rule establishes the criteria which EPA will apply and the procedures it will follow in its evaluation of application for a modification.	Apr. 25, 1978	December 1978	Tom O'Farrell (WH-551). Environmental Protection Agency, Washington, D.C. 20460, 202-426-8976.
40 CFR 124 *Extension of Pollution Control Deadlines for Publicly Owned Treatment Works and Other Point Sources Planning to Discharge to Those Publicly Own Treatment Works.* CWA 301(j). This regulation establishes criteria which EPA and NPDES States will use in reviewing requests for 301(i) extensions from the July 1, 1977, treatment requirements.	May 16, 1978, interim final	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 125 *Requirements for Application for 301 (c) and (g) Variances.* CWA 301(j)(1)(B). These regulations require discharges desiring 301 (c) and (g) variances to file initial applications by Sept. 25, 1978, or 270 days after promulgation of BAT limitations whichever is later .	Sept. 13, 1978, interim final	January 1979, will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Scott Slesinger (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
Effluent guidelines representing best available treatment technology, new source performance standards, and pretreatment standards are being developed for the following industries to comply with the Act and a court order mandating control of certain toxic substances in industrial effluents. CWA 301, 304, 306, and 307.			
40 CFR 420 *Iron and Steel Manufacturing*	November 1979	May 1980	Ernst Hall (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2576.
40 CFR 435 *Petroleum Refining*	March 1979	October 1979	Robert Dellinger (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 429 *Timber Products Processing*	May 1979	December 1979	John Riley (WH-552). Environmental Potection Agency, Washington, D.C. 20460, 202-426-5554.
40 CFR 423 **Steam Electric Power Plants*	do	do	John Lum (WH-552). Environmental Protection Agency, Washington, D.C. 20460 202-426-4617
40 CFR 426 *Leather Tanning and Finishing*	January 1979	August 1979	William Sonnett (WH-552). Environmental Protection Agency, Washington, D.C. 20460 202-426-2440.
40 CFR 421 *Nonferrous Metals Manufacturing*	August 1979	March 1980	Patricia Williams (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2586.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT			
40 CFR 46 *Paint and Ink Formulation*	September 1979	April 1980	Richard Gigger (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2583.
40 CFR 448 *Printing and Publishing Services*	November 1979	June 1980	Do.
40 CFR 440 *Ore Mining and Dressing*	......do	July 1980	Gail Coad (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2503.
40 CFR 434 *Coal Mining*	December 1979	June 1980	William Telliard (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2726.
40 CFR 414 *Organic Chemicals Manufacturing*	January 1980	August 1980	Paul Farenthold (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 415 *Inorganic Chemicals Manufacturing*	September 1979	April 1980	Walter Hunt (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2724.
40 CFR 410 *Textile Mills*	May 1979	December 1979	James Gallup (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2554.
40 CFR 416 *Plastics and Synthetic Material*	January 1980	August 1980	Paul Fahrenthold (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 430 *Pulp and Paper*	February 1980	.....do	Bob Dellinger (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2554.
40 CFR 428 *Rubber Processing*	June 1979	January 1980	Do.
40 CFR 417 *Soap and Detergents Manufacturing*	July 1980	July 1981	Sammy Ng (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2503.
40 CFR 444 *Auto and Other Laundries*	December 1979	July 1980	Richard Gigger (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2583.
40 CFR 456 *Miscellaneous Chemicals—Adhesives and Sealants.*	February 1980	August 1980	Elwood Forsht (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2707.
40 CFR 457 *Miscellaneous Chemicals—Explosives Manufacturing.*	December 1979	July 1980	Elwood Martin (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2440.
40 CFR 454 *Miscellaneous Chemicals—Gum and Wood.*	August 1979	March 1980	Richard Williams (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2555.
40 CFR 455 *Miscellaneous Chemicals—Pesticides*	March 1980	October 1980	George Jett (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 439 *Miscellaneous Chemicals—Pharmaceuticals.*	December 1979	July 1980	Joe Vitalis (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2497.
40 CFR 413 *Electroplating*	March 1980	October 1980	Maurice Owens (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-755-1331.
40 CFR 459 *Machinery and Mechanical Products—Photographic Equipment and Supplies.*	February 1980	August 1980	Ernst Hall (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2576.
40 CFR 433 *Machinery and Mechanical Products—Mechanical Products.*	August 1980	March 1981	Do.
40 CFR 469 *Machinery and Mechanical Products—Electrical and Electronic Components.*	March 1980	October 1980	Do.
40 CFR 464 *Machinery and Mechanical Products—Foundry Operations.*	October 1979	May 1980	Do.
40 CFR 468 *Machinery and Mechanical Products—Copper and Copper Alloy Products.*	April 1980	November 1980	Do.
40 CFR 461 *Machinery and Mechanical Products—Battery Manufacturing.*	March 1980	October 1980	Do.
40 CFR 465 *Machinery and Mechanical Products—Coil Coating.*	August 1979	March 1980	Do.
40 CFR 463 *Machinery and Mechanical Products—Plastics Processing.*	October 1980	May 1981	Do.
40 CFR 466 *Machinery and Mechanical Products—Porcelain Enamel.*	October 1979	May 1980	Ernst Hall (WH-552). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2576.
40 CFR 467 *Machinery and Mechanical Products—Aluminum Forming.*	March 1980	October 1980	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT			
40 CFR 124 and 125 *Veto Modification.* CWA 301(b)(a), 304(1), 307(a), 402(b), 501(a). This regulation revises existing regulations to conform to the requirements in the NRDC versus Train Consent Decree June 8, 1976 and to clarify the procedures under which EPA will exercise its power to object to (veto) State issued NPDES permits.	Jan. 6, 1978	May 23, 1978	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 125 *Substantive Criteria for 301(c) and (g) Variances from BAT Requirements.* CWA 301 (c) and (g). This criteria will establish information necessary for assessment of economic and environmental variance requests.	January 1979	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Do.
40 CFR 130.17 **Revision of Water Quality Standards Regulation (Part 130.17).* CWA 303. This regulation will amend the existing regulation covering State Water Quality Standards to establish requirements regarding States adopting standards for toxic pollutants when EPA has issued national ambient water quality criteria for those pollutants. One effect of this amendment will be that dischargers (both municipal and industrial) may have to install treatment technology beyond that required by Best Available Wastewater Treatment Technology (BPWTT) or Best Available Technology (BAT) guidelines.	March 1979	March 1980	Ken Mackenthun (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0100.
40 CFR *Quality Criteria for Water: Volume II.* CWA 304(a). Ambient water quality criteria will be established for 65 pollutants.	(29 pollutants) March 1979 (36 pollutants) July 1979	September 1979 December 1979	Do.
40 CFR 400 to 469 *Secondary Industry Review.* CWA 304(b). This regulation will provide for promulgated of Best Practicable Conventional Pollutant Control Technology (BTC) for certain subcategories of the "secondary industries" industries not covered by the NRDC Settlement Agreement. For other subcategories, Best Available Technology (BAT) limits will be suspended. The methodology that will be used for BCT for secondary industries will also be applied to BCT for primary industries at the time that BAT regulations are established.	Aug. 23, 1978	April 1979	Dave Pege (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2617.
40 CFR 125 *Criteria and Standards for Imposing Best Management Practices for Ancillary Industrial Activities.* CWA 304(e). This regulation will indicate how "best management practices" for on-site industrial activities may be imposed in NPDES permits to prevent release of toxic and hazardous pollutants to surface waters.	Sept. 1, 1978	Will be incorporated into NPDES program regulations 40 CFR 122 to 125.	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
General Pretreatment Regulations for Existing and New Sources of Pollution. CWA 307(b)(1). This regulation establishes requirements and procedures for a general pretreatment program including development of State and local programs.		June 26, 1978	Steve Heare (WH-586). Environmental Protection Agency, Washington, D.C. 20460, 202-755-6885.
40 CFR 117 *Revision of Hazardous Substances Discharge Regulations.* CWA 311. As a result of amendments of sec. 311, pts. 117 and 119 will be withdrawn and pt. 118 revised, principally to clarify which dischargers will be subject to the provisions of sec. 311.	November 1978	December 1978	Colburn T. Cherney (A-131). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0760.
40 CFR *Oil Spill Liability.* CWA 311(q). This rule will establish maximum limits of liability for fixed non-transportation related facilities which may face cleanup liabilities under sec. 311.	September 1979	June 1980	Joseph Lewis (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-245-0581.
40 CFR 140 *Marine Sanitation Devices.* CWA 312. These rules will establish secondary treatment or equivalent for ships navigating the Great Lakes.			Jonathan Amson (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-245-3036.
40 CFR 140 *Drinking Water Intake Zone Exemptions.* CWA 312. These regulations, which will establish guidance for State no-discharge prohibitions for drinking water intake zones, are a part of the Marine Sanitation Devices regulations.			Do.
40 CFR 35 *Clean Lakes.* CWA 314. These rules will establish procedures for administering grants to the States for the purpose of restoring lakes.	December 1978	February 1979	Robert Johnson (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-472-3400.
40 CFR 151 *Hazardous Substances Pollution Prevention for Facilities Subject to Permitting Requirements.* CWA 402. This proposed regulation sets forth requirements for Spill Prevention Control and Countermeasure Plans for nontransportation related facilities which handle hazardous substances and are subject to NPDES permits.	Sept. 1, 1978	February 1979	Thomas J. Charlton (WH-548). Environmental Protection Agency, Washington, D.C. 20460, 202-245-3045.
40 CFR *NPDES Program.* CWA 402. This regulation revises, updates, clarifies, and reorganizes existing NPDES regulations.	Aug. 21, 1978	January 1979	Ed Kramer (EN-336). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0750.
40 CFR 124 *Veto Modification.* CWA 402. These regulations will establish the use of short-term permits as the preferred mechanism for assuring compliance with NRDC Consent Decree.	May 23, 1978		Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE CLEAN WATER ACT (Federal Water Pollution Control Act as amended by the Clean Water Act Amendments of 1977)			
40 CFR 231 *Ocean Discharge Criteria.* CWA 403(c). These guidelines pertain to discharges to the ocean. They are based on prevention of environmental degradation of waters of the territorial seas, the contiguous zone, and the oceans. Both industrial and municipal dischargers would have to meet these criteria.	April 1979	December 1979	Tom O'Farrell (WH-551). Environmental Protection Agency, Washington, D.C. 20460, 202-426-8976.
40 CFR 230 *Guidelines to Protect the Aquatic Environment, Including Wetlands, From the Discharge of Dredged or Fill Material.* CWA 404(b)(1). These guidelines must be considered in the issuance of individual and general permits, in the preparation of Environmental Impact Statements (EIS's) for Federal activities specifically authorized by the Congress, and in preparation of Best Management Practices (BMP's) under the State 208(b)(4)(B) program. Failure to comply with these guidelines justifies denial of permit applications and return of State permit programs to the Corps of Engineers. Sept. 5, 1975, interim-final guidelines are being revised and expanded by this effort.	January 1979	July 1979	John Crowder (WH-585). Environmental Protection Agency, Washington, D.C. 20460, 202-472-3400.
40 CFR 123 *Procedural Regulations Concerning State Qualifications for Assuming the Section 404 Permit Program.* CWA 404(g). Certain requirements that must be met for States to assume permitting authority under sec. 404(g) such as codification of State laws and certifications by the State attorney general are similar to NPDES requirements. Therefore, the appropriate parts of sec. 404(g) have been included in the proposed revision of existing regulations for NPDES in pt. 123.	Oct. 21, 1978	December 1978	Office of Water Enforcement. Environmental Protection Agency, Washington, D.C. 20460, 202-755-0440.
40 CFR 127 *Procedural Regulations for Exercising the 404(c) Veto.* CWA 404(c). These regulations will establish the procedures for preventing the discharge of dredged or fill material into a defined area of the waters of the United States.	January 1979	July 1979	John Crowder. Environmental Protection Agency, Washington, D.C. 20460, 202-472-3400.
40 CFR 126 *Substantive Regulations Concerning State Implementation of Section 404 Permit Program.* CWA 404(g), (h). States may propose for approval by the Administrator of EPA a sec. 404 program in lieu of the Federal for permitting the discharge of dredge or fill material in certain waters of the United States. These regulations described the components of a State permit program that will be minimally acceptable to the Administrator.	January 1979	July 1979	Do.
40 CFR 258 *Sewage Sludge Disposal.* CWA 405 and RCRA 4004. These regulations are to assure that municipal sludge is managed in a manner that will protect public health and the environment and that valuable resources are conserved through beneficial utilization where practicable.	July 1979	August 1980	Bruce Weddle (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.
THE SAFE DRINKING WATER ACT			
40 CFR 141 **Control of Organic Chemical Contaminants in Drinking Water.* SDWA 1412. The first part of this regulation sets a maximum contaminant levels for trihalomethanes and the second part establishes a required treatment techniques for synthetic organic chemicals.	Feb. 9, 1978	January 1979	Joe Cotruvo (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-472-5016.
40 CFR 141 *Technical Amendments to the National Interim-Primary Drinking Water Regulations.* SDWA 1412. These regulations will be adjustments to the previously published National Interim-Primary Drinking Water regulations.	December 1978	April 1979	Do.
40 CFR 143 *National Secondary Drinking Water.* SDWA 1412(C). These regulations will be nonenforceable guidelines on esthetic drinking water quality.	Mar. 31, 1977	February 1979	Frank Bell (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-472-6820.
40 CFR 146 *Underground Water Source Protection Program Grants.* SDWA 1443(b). This regulation would set forth requirements for underground injection control grants.	Aug. 31, 1976	Oct. 12, 1978	Tom Belk (WH-550). Environmental Protection Agency, Washington, D.C. 20460, 202-426-3934.
40 CFR 146 *Underground Water Source Protection Program.* SDWA 1421(a). These regulations are intended to protect groundwater drinking supplies from contamination caused by improper underground injection of fluids. The vast majority of injection practices occurs in the oil and gas industry. States can apply for primary enforcement authority if they meet the minimum criteria specified in the regulations. The regulations can require a permit program to ensure that a case-by-case determination is made.	January 1979 (reproposal)	May 1979	Do.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE NOISE CONTROL ACT			
40 CFR 205 *Light Duty Motor Vehicles.* NCA 5. This action will result in a decision regarding whether or not light duty vehicles are or are not a major noise source. If they are found to be, then resulting noise emission and/or noise labeling standards will be prepared.	Work plan under development		William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 205 *Buses.* NCA 5/6. This regulation will set noise emission standards for new inter-State, inner-city, and schoolbuses.	Sept. 12, 1977	June 1979	Do.
40 CFR 204 *Truckmounted Solid Waste Compactor.* NCA 5/6. The regulations sets noise emission standards for solid waste compactors.	Aug. 26, 1977	June 1979	Kenneth Feith (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-2710.
CFR 206, 207 *Lawnmowers.* NCA 5/6. The regulation sets noise emission standards for new lawnmowers.	October 1979	October 1980	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 204 *Pavement Breakers and Rock Drills.* NCA 5/6. The regulation sets noise emission standards for new pavement breakers and rock drills.	June 1979	June 1980	Kenneth Feith (AW—490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-2710.
40 CFR 204 *Truck Transported Refrigeration Units.* NCA 5/6. The regulation sets noise emission standards for new truck transport refrigeration units.	Developmental work halted pending analysis of regulatory alternatives.		Do.
40 CFR 204 *Wheel and Crawler Tractors.* NCA 5/6. The regulation sets a noise emission standard for new wheel and crawler tractors.	July 11, 1977	June 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 205 *Motorcycles.* NCA 5/6. This regulation sets noise emission standards for motorcycles and replacement exhaust systems.	Feb. 15, 1978	October 1979	William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 211 *Labeling: Hearing Protectors.* NCA 8. The regulation requires the labeling of hearing protectors.	June 22, 1977	January 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 211 *Labeling: General.* NCA 8. The regulation establishes general labeling provisions.	......do	......do	Do.
40 CFR 210 *Administrative Hearing Procedures.* NCA 11. These procedures will apply to hearings for the issuance of remedial orders under sec. 11(d) of the Act. As mandated, these are adjudicatory hearings under the Administrative Procedure Act, 5 U.S.C. 554.	Aug. 3, 1978	December 1978	Jim Kerr (EN-387). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7410.
40 CFR 203 *Low Noise Emission Products.* NCA 15. This regulation allows a determination of when a product is a low noise emission product and whether it is suitable for special consideration in Federal purchasing.	May 27, 1977	May 1979	Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 205 *Interstate Rail Carriers.* NCA 17. This regulation sets noise emission standards for railroad "facilities." EPA has prepared this regulation as a result of a successful lawsuit brought by the Association of American Railroads which said EPA's regulations setting noise emission standards for locomotives and cars failed to address the related problem of noise from facilities such as railroad yards. The Court ordered EPA to adopt final regulations controlling railroad facilities—everything in addition to the cars and locomotives.	December 1978	February 1979	William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.
40 CFR 201 *Special Local Conditions.* NCA 17(c)2/18(c)2. The regulation establishes procedures permitting adoption by a State or otherwise preempted State and local rail and motor carrier noise regulations when necessitated by special local conditions..	Nov. 29, 1976		Henry Thomas (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7743.
40 CFR 202 *Interstate Motor Carrier.* NCA 18. This action will update the noise emission standards for interstate motor carriers to reflect increased knowledge about available noise abatement technology.	Work plan under development		William Roper (AW-490). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7747.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in Federal Register	Final date in Federal Register	Contact person and address
THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT			
40 CFR 162 **Pesticide Registration Guidelines:*			
Introduction. FIFRA 3. This subpart B (will become A) includes the general purposes of all of the guidelines, degree of flexibility in requirements and in interim data usage, definition of terms used throughout the guidelines, and requirements for retention of data and test samples at laboratories.	July 10, 1978	April 1979	Bill Preston (TS-769). Environmental Protection Agency, Washington, D.C. 20460, 703-557-7351.
Experimental Use Permits. FIFRA 3. This subpart A (will become subpart C) specifies the data that must be submitted in support of an application for an experimental use permit.			Do.
Chemistry Requirements. FIFRA 3. This subpart D covers data submission requirements relating to chemistry of pesticide products' active ingredients and their formulation components and manufacturing impurities. (Chemical study requirements dealing with environmental fate of pesticides may be included here or be moved to a new subpart.).	July 10, 1978	April 1979	Do.
Hazard Evaluation: Wildlife and Aquatic Organisms. FIFRA 3. This subpart E outlines the data submission requirements for studies of pesticide effects on birds, wild mammals, fish, and other aquatic animals.	do	May 1979	Do.
Hazard Evaluation: Humans and Domestic Animals. FIFRA 3. This subpart F delineates the data submission requirements for studies of pesticide effects in laboratory animals involving oral, dermal, and inhalation uptake routes, acute, subchronic, anbd chronic exposures, and including local or systemic injury and maladies such as oncogenic, teratogenic, mutagenic, and neurotoxic effects.	Aug. 22, 1978	June 1979	Do.
Product Performance. FIFRA 3. This subpart G specifies the data submission requirements that registrants must submit to demonstrate that the prospective pesticide product will control the pests or control undesired growth or behavior as specified in label claims.	December 1978	August 1979	Do.
Label Development. FIFRA 3. This subpart H describes all essential parts of a pesticide product label, how labeling and label statements must comply with the Act, and how claims and directions must correspond to evidence presented or on hand in data on efficacy and safety.	March 1979	October 1979	Do.
40 CFR 162 *Pesticide Use Restrictions.* FIFRA 3. This regulation will classify pesticide uses for restricted use..	December 1978	January 1979	Walt Waldrop (TS-770). Environmental Protection Agency, Washington, D.C. 0460, 202-755-7014.
Conditional Registration Regulation. FIFRA 3(c)(7) (A) and (B). This interim/final regulation would establish procedures for conditional registration of pesticide products which are identical or substantially similar to those currently registered or new uses of existing pesticide products.		February 1979	Bob Rose (TS-767). Environmental Protection Agency, Washington, D.C. 20460, 202-426-2510.
Conditional Registration Regulation. FIFRA 3(c)(7)(C). This regulation provides for the conditional registration of new chemicals when certain data are missing.	July 1979		Do.
40 CFR 162.9, 173 *Registration Data Compensation.* FIFRA 3(C)(1)(D). These rules provide for compensation when one pesticide registrant relies on test data generated by another registrant.	June 21, 1977	February 1979	Ed Gray (A-132). Environmental Protection Agency, Washington, D.C. 20460, 202-755-0846.
40 CFR 172 *State Experimental Use Permits.* FIFRA (5)f. The regulation defines the scope of State jurisdiction to allow experimental uses of pesticides.	Sept. 30, 1975, interim final		Phil Gray (TS-770). Environmental Protection Agency, Washington, D.C. 20460, 202-755-7014.
40 CFR 165 *Storage and Disposal Practices (Prohibition).* FIFRA 19. These rules will prohibit dangerous or environmentally unsound pesticide storage practices.	Oct. 15, 1974	Will not be issued	John Lehman (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9185.
40 CFR 162 *State Registration to Meet Special Local Needs.* FIFRA 24(c). This part defines the scope of State jurisdiction over the registration of pesticides.	Sept. 3, 1975	March 1979	Phil Gray (TS-770). Environmental Protection Agency, Washington, D.C. 20460, 202-755-7014.
40 CFR 162.16 *Pesticide Special Packaging Regulations.* FIFRA 25. The rule prescribes when and what form of child-proof packaging is required.	Feb. 16, 1977	December 1978	Maureen Grimmer (TS-766). Environmental Protection Agency, Washington, D.C. 20460, 202-755-8030.
40 CFR 162 *Exemption of New Human Drugs.* FIFRA 25(c)(2). This part would exempt from FIFRA pesticides that are also new drugs regulated by FDA.	Oct. 13, 1978	do	Dave Brandewein (TS-766). Environmental Protection Agency, Washington, D.C. 20460, 202-755-8037.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE ATOMIC ENERGY ACT			
Protective Action Guidelines for Nuclear Emergencies. AEA 274(h). This is a guidance for emergency response plans in the event of a nuclear accident, i.e. effluent release from a nuclear reactor.	September 1979	February 1980	Jim Hardin (AW-460) Environmental Protection Agency, Washington, D.C. 20460, 703-557-8610.
Guidance for Occupational Radiation Exposure. AEA 274(h). This guidance will update existing (1960) radiation occupational exposure limits for workers at Federal facilities and those facilities inspected by Federal agencies.	January 1979	June 1979	Luis Garcia (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8224.
Transuranic Elements. AEA 274(h). This guidance to Federal agencies establishes dose rate limits for persons exposed to transuranium elements in the general environment. The final guidance is to be signed by the President.	Nov. 3, 1977	January 1979	Gordon Burley (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8619.
*_Environmental Standards for High-Level Radioactive Wastes._ AEA 274(h). The regulation will set standards for release of radioactivity to the environment as a result of storage of waste isotopes.	January 1979	July 1979	Jim Martin (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8927.
Environmental Criteria for Radioactive Wastes. AEA 274(h). The criteria are general guidance as to what constitutes radioactive waste and factors to be considered in evaluating disposal modes and sites.	November 1978	April 1979	Harry Pettengill (AW-460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8927.
Florida Phosphate Tailings. PHSA 301. A 1975 commitment to the Governor of Florida by the Administrator requries EPA to establish guidelines as to what to do (1) about existing houses on uranius "contaminated" land; (2) about new construction on such land.	January 1979	July 1979	Joe Fitzgerald (AW0460). Environmental Protection Agency, Washington, D.C. 20460, 703-557-8224.
THE RESOURCE CONSERVATION AND RECOVERY ACT			
40 CFR 241 _Guidelines for Solid Waste Management Landspreading Practices._ RCRA 1008(a). These are nonregulatory technical guidelines on landscaping practices for the beneficial use of solid waste as soil conditioner and plant nutrient.			Bruce Weddle (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.
40 CFR 250 _Hazardous Waste Criteria—Identification and Listing._ RCRA 3001. These regulations define those wastes that will be controlled under the nationwide hazardous waste management program. Criteria are provided for identifying characteristics of hazardous waste and for listing hazardous waste. The selected characteristics are: ignitability, corrosiveness, reactivity, and toxicity. Testing procedures are included for determination of whether a waste meets the described characteristics. The regulation also lists certain hazardous wastes or processes which are presumed to generate hazardous wastes. Also, means are provided for demonstration of noninclusion in the subtitle C system.	January 1979	January 1980	Alan Corson (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9187.
40 CFR 250 *_Standards for Generators of Hazardous Wastes._ RCRA 3002. This regulation establishes national standards for generators of hazardous wastes, covering such items as recordkeeping, containerization and labeling, waste identification, and reporting. This regulation also contains provisions for a hazardous waste manifest system.	do	do	Harry Trask (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9187.
40 CFR 250 _Standards for Transporters of Hazardous Wastes._ RCRA 3003. These national standards make transporters of hazardous wastes responsible for shipping only properly labeled containers and only to permitted facilities.	Apr. 28, 1978	do	Do.
40 CFR 250 *_Standards for Hazardous Waste Treatment, Storage and Disposal Facilities._ RCRA 3004. The standards establish technical performance standards for hazardous waste management facilities, relative to operating practices, location, and design. The contain provisions for protection of surface water, ground water, and air quality.	January 1979	do	John Schaum (WH-565). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9200.
40 CFR 250 _Permit Regulations for Hazardous Waste Treatment, Storage, and Disposal Facilities._ RCRA 3005. This regulation establishes a permit program to assure uniform control by States (or EPA) over hazardous waste management facilities.	do	do	Sam Morekas (WH-564). Environmental Protection Agency, Washington, D.C. 20460, 202-755-9120.

MAJOR EPA REGULATIONS UNDER CONSIDERATION—Continued

Name and description of regulation	Proposal date in FEDERAL REGISTER	Final date in FEDERAL REGISTER	Contact person and address
THE RESOURCE CONSERVATION AND RECOVERY ACT			
40 CFR 250 *Guidelines for State Hazardous Waste Programs*. RCRA 3006. These guidelines are to assist States in the development of their own hazardous waste regulatory programs. The guidelines also specify minimum requirements States must meet in order to be authorized by EPA to implement their hazardous waste programs.	Feb. 1, 1978	January 1979	Dan Derkics (WH-565), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9190.
40 CFR 250 *Notification System for Hazardous Waste Generators, Transporters, Storers, Treaters, and Disposers*. RCRA 3010. The regulation describes the one-time notification requirement for generators, transporters, treaters, storers, and disposers of hazardous waste, which will bring them to the attention of the persons administering RCRA's hazardous waste program.	July 11, 1978	August 1979	Timothy Fields (WH-565), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9206.
40 CFR 256 *Guidelines for State Solid Waste Programs*. RCRA 4002(b). These guidelines are to assist States in the development and implementation of solid waste management programs.	Aug. 28, 1978	June 1979	George Garland (WH-565), Environmental Protection Agency, 202-755-9125.
40 CFR 257 *Criteria for Classification of Solid Waste and Disposal Facilities*. RCRA 4004(a). These criteria provide a basis against which solid waste land disposal facilities can be evaluated in order to determine probability of adverse effects on health or the environment.	Feb. 6, 1978	July 1979	Kenneth Shuster (WH-564), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9116.
Guidelines for Federal Procurement Practices. RCRA 6002(e). These guidelines will assist Federal agencies to comply with the RCRA's requirement that procured materials be composed of the highest percentage of recovered materials practicable:			Stephen Lingle (WH-563), Environmental Protection Agency, Washington, D.C. 20460, 202-755-9140.
Utilization of Fly Ash and Slag	April 1979	July 1979	
Use of Recycled Paper in Paper Products	June 1979	September 1979	
Use of Waste in Construction Products	July 1979	October 1979	
THE TOXIC SUBSTANCE CONTROL ACT			
40 CFR 740 to— **Testing of Chemical Substances and Mixtures*. TSCA 4. These regulations require testing of chemical substances that may present an unreasonable risk to human health or the environment, or are produced in substantial quantities but are not supported by adequate test data. EPA is preparing two testing regulations: on cogenicity testing and environmental fate testing.	December 1978	Mar. 1979, 749	Norbert Page (TS-792), Environmental Protection Agency, Washington, D.C. 20460, 202-755-6841.
40 CFR 720 *Premanufacture Notification*. TSCA 5. This regulation will establish the procedure whereby a company will notify EPA of its intent to manufacture a new chemical. The regulation will prescribe the required premanufacture notification form, describe the procedure for EPA review, and contain testing guidelines.	December 1978	April 1979	Blake Biles (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-5432.
40 CFR 761 *PCB's Manufacture and Distribution*. TSCA 6. This regulation bans the manufacturing and distribution of PCBs and products containing PCBs.	June 7, 1978	January 1979	Peter Principe (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0920.
Control of Polybrominated Biphenyls. TSCA 6. The regulation would control the use of polybrominated biphenyls.	January 1979	July 1979	Lucy Sibold (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-8963.
Chlorofluorocarbon Emissions. TSCA 6. This regulation would apply to nonaerosol uses of chlorofluorocarbons.	To be determined		Ferial Bishop (TS-794), Environmental Protection Agency, Washington, D.C. 20460, 202-755-8963.
40 CFR 730 *Reporting on Substances Recommended for Testing*. TSCA 8(d). The regulation requires reporting of existing health and safety studies for chemical categories as recommended for testing.	May 1979	December 1979	Ed Brooks (TS-793), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0932.
40 CFR 720 *Records of Adverse Reaction*. TSCA 8(e). The regulation requires industry to keep records of allegations of significant adverse health and environmental reactions to its chemical products.	March 1979	October 1979	Do.
40 CFR *Procedures for Export Notification*. TSCA 12(b). These rules tell exporters how and when to submit export notifications.	December 1978	May 1979	Do.
40 CFR 22 *Consolidated Rules of Practice Governing the Assessment of Civil Penalties*. TSCA 16. These rules would be promulgated under the authority of FIFRA 14, RCRA 3008, Marine Protection Research and Sanctuaries Act (MPRSA) 105, CAA 211, and TSCA 16.	Aug. 4, 1978, interim final	October 1979	Terrell Hunt (EN-342), Environmental Protection Agency, Washington, D.C. 20460, 202-755-0970.

[FR Doc. 78-33253 Filed 11-29-78; 8:45 am]

☆ U. S. GOVERNMENT PRINTING OFFICE : 1979 620-007/3761